UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

CITY OF ALLENTOWN, PENNSYLVANIA, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION; CARDINAL HEALTH, INC.; McKESSON CORPORATION; PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICAL USA, INC.; CEPHALON, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; PAR PHARMACEUTICAL, INC.; PAR PHARMACEUTICAL COMPANIES, INC. F/K/A PAR PHARMACEUTICAL HOLDINGS, INC.; ALLERGAN PLC f/k/a ACTAVIS PLC, f/k/a WATSON PHARMACEUTICALS, INC., f/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; MALLINCKRODT PLC; MALLINCKRODT LLC., and; SPECGX LLC Defendants.	CIVIL ACTION NO.: **COMPLAINT** Complaint for RICO; Public Nuisance; Negligence and Negligent Misrepresentation; Negligence Per Se; Civil Conspiracy; Unjust Enrichment; and Fraud and Fraudulent Misrepresentation **JURY TRIAL DEMANDED AND ENDORSED HEREON**

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The City of Allentown, Pennsylvania ("Plaintiff" or the "City"), by and through its undersigned counsel, upon knowledge as to itself and upon information and belief as to all other matters, brings this Complaint against defendants AmerisourceBergen Drug Corporation; McKesson Corporation; Cardinal Health, Inc.; Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceutical Industries, LTD.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Par Pharmaceutical Inc.; Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.; Allergan PLC f/k/a Actavis PLC, f/k/a Watson Pharmaceuticals, Inc., f/k/a Actavis, Inc.; Watson Laboratories, Inc.; Actavis, LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Mallinckrodt plc; Mallinckrodt LLC; and SpecGX LLC (collectively "Defendants") and alleges as follows:

I. Introduction

1. Plaintiff brings this civil action to eliminate the hazard to public health and safety in Allentown caused by the national opioid epidemic, to abate the nuisance caused thereby, and to recoup economic losses attributable to Defendants' false, deceptive, and unfair marketing and/or unlawful diversion of prescription opioids. Such economic damages were foreseeable to Defendants and were sustained because of Defendants' intentional and/or unlawful actions and omissions.

2. The United States is in the midst of a national epidemic of drug overdose deaths and addictions resulting from the widespread abuse of opioids.[1]

3. Pennsylvania – which is about to declare its seventh renewal of its disaster declaration over this crisis – has been hit particularly hard, with the third highest rate of drug

[1] As used herein, the term "opioid" refers to the entire family of opiate drugs including natural, synthetic and semi-synthetic opiates.

overdose deaths in the United States as of 2017 (the last year for which full statewide data are available).[2]

4. This crisis has devastated Allentown, which has lost hundreds of its residents to fatal overdoses since the onset of the opioid epidemic.

5. This opioid epidemic is directly related to the increase in prescriptions for powerful opioid drugs, which are widely diverted and improperly used.

6. Plaintiff brings this action against certain manufacturers of prescription opioids. These manufacturers aggressively pushed highly addictive, dangerous opioids, falsely representing to doctors that patients would only rarely succumb to drug addiction. These pharmaceutical companies aggressively advertised to and persuaded doctors to prescribe highly addictive, dangerous opioids, and turned patients into drug addicts for their own corporate profit. Such actions were intentional, unlawful, negligent and/or were performed with reckless and wanton disregard for the safety of those patients.

7. Plaintiff also brings this action against certain wholesale distributors of these highly addictive drugs. The distributors and manufacturers intentionally and/or unlawfully breached their legal duties under federal and state law to monitor, detect, investigate, refuse, and report suspicious orders of prescription opioids.

II. Parties

A. Plaintiff

8. The City of Allentown is located in Lehigh County and operates as a Home Rule City of the Third Class under the Pennsylvania Code. Plaintiff's annual budget provides for

[2] https://www.inquirer.com/health/pennsylvania-overdose-deaths-among-highest-in-nation-study-20190612.html

expenditures in excess of $100 million for its operations and provision of a range of social services.

9. At all times material hereto, Plaintiff has expended resources to provide services and operations for the protection of the health, safety and public welfare of the City and its residents through a variety of public entities, including the City's Bureau of Health, Emergency Medical Services (EMS), and the Allentown Police Department. At all times material hereto, Plaintiff has provided benefits to its employees and employees' families, including but not limited to health, dental and life insurance benefits. Further, Plaintiff has provided appropriations to fund public health and welfare needs within the City, including the City's Heroin/Opioid Prevention Education (HOPE) training and Heroin/Opioid Task Force.

10. In the City, opioid abuse, addiction, morbidity, and mortality have created a serious public health and safety crisis and are a public nuisance.

11. The distribution and diversion of opioids into the State and into the City and surrounding areas (collectively, "Plaintiff's Community"), created the foreseeable opioid crisis and opioid public nuisance for which Plaintiff here seeks relief.

12. Plaintiff directly and foreseeably sustained all economic damages alleged herein. Defendants' conduct has exacted a financial burden for which the Plaintiff seeks relief. Categories of past and continuing sustained damages include, *inter alia*: (1) costs incurred by Allentown's EMS, the Allentown Fire Department, and other city departments in responding to and treating opioid-related emergencies, including opioid overdoses; (2) costs incurred by the Allentown Police Department and other city departments in addressing law enforcement and public safety threats caused by the opioid epidemic; (3) costs associated with providing medical care, therapeutic care, prescription drug purchases, and other treatments for City employees and

others who receive health insurance from the City, and; (4) costs incurred by Allentown's Bureau of Health and other city departments in connection with providing health services, social services, and preventative education to mitigate the harms caused by the opioid epidemic in Allentown. Plaintiff has suffered and continues to suffer these costs.

13. Plaintiff also seeks to abate the epidemic that the Defendants' wrongful and/or unlawful conduct has created.

14. Plaintiff is authorized to bring the causes of action brought herein.

15. Plaintiff has standing to recover damages incurred as a result of the Defendants' actions and omissions. Plaintiff has standing to bring all claims pled herein.

B. Defendants and Other Conspirators

1. Marketing Conspirators

16. At all relevant times, the Marketing Conspirators (as defined below) have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of prescription opioid drugs. The Marketing Conspirators, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

a. Purdue

17. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut, and THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut. PURDUE PHARMA L.P., PURDUE PHARMA INC. and

THE PURDUE FREDERICK COMPANY are collectively referred to as "Purdue."

18. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States. More than half of Purdue's revenue emanates from the sale of opioids.[3] OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual nationwide sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

19. In 2007, Purdue and three top executives pleaded guilty to federal criminal charges in connection with fraudulently promoting OxyContin as non-addictive and appropriate for chronic pain. Under the plea agreement, Purdue agreed to pay over $600 million in criminal and civil penalties – one of the largest settlements in history for a drug company's marketing misconduct.[4] Purdue's Chief Executive Officer, General Counsel, and Chief Medical Officer also pleaded guilty and agreed to pay a total of $34.5 million in penalties.[5] As part of its guilty plea, Purdue admitted that between 1995 and 2001, certain of its supervisors and employees fraudulently "marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications" between 1995 and 2001.[6] Purdue acknowledged specific examples of fraud and deception including the following:

> a. [Purdue] told Purdue sales representatives they could tell health care providers that OxyContin potentially creates less chance for addiction than immediate-release opioids;

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[3] Esme Deprez, *The Lawyer Who Beat Big Tobacco Takes on the Opioid Industry*, Bloomberg Businessweek (Oct. 5, 2017), *available at* https://www.bloomberg.com/news/features/2017-10-05/the-lawyer-who-beat-big-tobacco-takes-on-the-opioid-industry.
[4] https://archive.org/stream/279028-purdue-guilty-plea/279028-purdue-guilty-plea_djvu.txt.
[5] *Id*.
[6] *Id*.

> b. [Purdue] sponsored training that taught Purdue supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids;
>
> c. [Purdue] told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug; and
>
> d. [Purdue] told certain health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers. [7]

Notwithstanding the penalties described above, Purdue's wrongdoing not only continued but escalated.

20. On August 19, 2015, the New York Attorney General ("NYAG") entered into a settlement agreement with Purdue regarding Purdue's marketing of opioids. As part of the settlement, Purdue agreed to pay a monetary penalty and to provide on its websites certain information which it had failed to disclose in the past.[8]

21. In the settlement agreement, the NYAG noted that, from at least March 2014 to March 2015, a Purdue website failed to disclose that doctors who provided testimonials on the site were paid by Purdue. The NYAG concluded that Purdue's failure to disclose these financial connections misled consumers regarding the objectivity of the testimonials. The settlement agreement stated, in relevant part:

> Purdue maintains an unbranded pain management advocacy website, www.inthefaceofpain.com. From March 2014 to March 2015, the website received a total of 251,648 page views. Much of the video content on www.inthefaceofpain.com is also available on YouTube. . . .
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> Written and video testimonials from several dozen "Advocates," whose faces appear on the website and many of whom are HCPs [health care providers], comprise a central component of the site. For example, Dr. Russell Portenoy, the recipient of almost $4,000 from Purdue for meeting and travel costs, was quoted

[7] *Id*.
[8] NYAG-Purdue Settlement Agreement, Aug. 19, 2015, at pg. 15-17.

> on the website as follows: "The negative impact of unrelieved pain on the lives of individuals and their families, on the healthcare system, and on society at large is no longer a matter of debate. The unmet needs of millions of patients combine into a major public health concern. Although there have been substantive improvements during the past several decades, the problem remains profound and change will require enormous efforts at many levels. Pressure from patients and the larger public is a key element in creating momentum for change."
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> Although Purdue created the content on www.inthefaceofpain.com … the site creates the impression that it is neutral and unbiased. However, prior to this investigation, the website failed to disclose that from 2008 to 2013, Purdue made payments totaling almost $231,000, for speaker programs, advisory meetings and travel costs, to 11 of the Advocates whose testimonials appeared on the site. The videos on YouTube also fail to disclose Purdue's payments to the Advocates.
>
> Purdue's failure to disclose its financial connections with certain Advocates has the potential to mislead consumers by failing to disclose the potential bias of these individuals.[9]

22. Notwithstanding these enforcement actions, Purdue continued to improperly market its own opioid products, and opioids generally, as alleged more fully herein. As summarized in an October 30, 2017 article in The New Yorker:

> Purdue has continued to fight aggressively against any measures that might limit the distribution of OxyContin, in a way that calls to mind the gun lobby's resistance to firearm regulations. Confronted with the prospect of modest, commonsense measures that might in any way impinge on the prescribing of painkillers, Purdue and its various allies have responded with alarm, suggesting that such steps will deny law-abiding pain patients access to medicine they desperately need. Mark Sullivan, a psychiatrist at the University of Washington, distilled the argument of Purdue: "Our product isn't dangerous – it's people who are dangerous."[10]

According to the article, Purdue continued to search for new users, both domestically and increasingly overseas, and in August 2015 even sought to market OxyContin to children as young as 11.[11]

23. In March 2019, Purdue Pharma agreed to pay the state of Oklahoma $270 million

[9] *Id*. at pg. 7-8.
[10] Patrick Radden Keefe, *The Family That Built an Empire of Pain*, The New Yorker (Oct. 30, 2017), available at https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain.
[11] *Id.*

to settle the state's lawsuit alleging that the company's false and unlawful marketing of opioids was responsible for the opioid epidemic in Oklahoma.

b. Cephalon

24. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a Delaware corporation and is a wholly owned subsidiary of Teva Ltd. in Pennsylvania. Teva USA acquired Cephalon in October 2011. Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are collectively referred to as "Cephalon."

25. Teva Ltd., Teva USA, and Cephalon, Inc. have worked together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events.

26. All of Cephalon's promotional websites, including those for Actiq and Fentora, display Teva Ltd.'s logo.[12] Teva Ltd.'s financial reports list Cephalon Inc.'s and Teva USA's sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon Inc. acquisition – attributed a 22% increase in its specialty medicine sales to "the inclusion of a

[12] *E.g.*, ACTIQ, http://www.actiq.com/ (displaying logo at bottom-left) (last visited Aug. 13, 2019).

full year of Cephalon's specialty sales," including *inter alia* sales of Fentora.[13]

27. Through interrelated operations like these, Teva Ltd. operates in the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon Inc. and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder.

28. Cephalon, Inc. manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora (which are both fentanyl-based) in the United States. Actiq has been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain."[14] Fentora has been approved by the FDA only for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."[15]

29. In 2008, Cephalon Inc. pleaded guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay $425 million.[16] The settlement resolved allegations that Cephalon Inc., *inter alia*, unlawfully

[13] Teva Ltd., Annual Report (Form 20-F) 62 (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf.
[14] *Highlights of Prescribing Information, ACTIQ® (fentanyl citrate) oral transmucosal lozenge, CII* (2009), https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s030lbl.pdf.
[15] *Highlights of Prescribing Information, FENTORA® (fentanyl citrate) buccal tablet, CII* (2011), https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s015lbl.pdf.
[16] Press Release, U.S. Dep't of Justice, Biopharmaceutical Company, Cephalon, to Pay $425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (Sept. 29, 2008), https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html.

promoted Actiq to non-cancer patients for migraines and other ailments and to patients who were not opioid tolerant even though "[t]he FDA had approved Actiq for use only in opioid-tolerant cancer patients."[17]

30. In May 2019, Teva Ltd, agreed to pay the state of Oklahoma $85 million to settle the state's lawsuit alleging that the company's false and unlawful marketing of opioids was responsible for the opioid epidemic in Oklahoma.

31. Notwithstanding this guilty plea and settlement described above, Cephalon continued to improperly market its own opioid products, and opioids generally, as alleged more fully herein.

c. Endo

32. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly-owned subsidiary of Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc. Defendant Par Pharmaceuticals Companies, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. are collectively referred to as "Par Pharmaceutical." Par Pharmaceutical was acquired by Endo International PLC in September 2015 and is an operating company of Endo International PLC. Endo Health Solutions Inc, Endo Pharmaceuticals Inc, Par Pharmaceutical, and their DEA registrant subsidiaries and affiliates are

[17] *Id.*

collectively referred to herein as "Endo.

33. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the United States. The sale of opioids generated Endo roughly $403 million of revenue in 2012, $657 million of revenue in 2014, and $486 million of revenues in 2016, when Endo's overall revenue reached $4 billion.

34. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States, by itself and through its subsidiaries, Par Pharmaceutical and Qualitest Pharmaceuticals, Inc.

35. On March 1, 2016, the NYAG entered into a settlement agreement with Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. regarding Endo's marketing and sales of Opana ER. As part of the settlement, Endo paid a $200,000 penalty and agreed to certain terms, described below.[18]

36. The NYAG found that Endo had no evidence for the claim on its website for Opana that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."[19]

37. The NYAG also found unwarranted Endo's statements in its training materials for sales representatives that addiction to opioids is not common, and that "symptoms of withdrawal do not indicate addiction."[20]

38. The NYAG further found that while Endo also trained its sales representatives to distinguish addiction from "pseudoaddiction," in fact the "pseudoaddiction" concept has never

[18] NYAG-Endo Settlement Agreement, March 1, 2016 at ¶ 54.
[19] *Id*. at ¶ 20.
[20] *Id*. at ¶ 22.

been empirically validated and has been abandoned by some of its proponents.[21] Finally, the NYAG noted that Endo omitted information about certain studies in its marketing pamphlets distributed to health care providers, and that Endo "omitted … adverse events from marketing pamphlets."[22]

39. As part of the NYAG settlement, Endo agreed to refrain from doing the following in New York: (i) "make statements that Opana ER or opioids generally are non-addictive," (ii) "make statements that most patients who take opioids do not become addicted," and (iii) "use the term 'pseudoaddiction' in any training or marketing."[23]

40. Endo's ability to engage in such deceptive marketing in other states across the country remained relatively encumbered.

41. In 2017, citing the "dangerous unintended consequences" of Opana ER, the FDA requested that Endo remove the drug from the market and stated that otherwise, the agency would formally withdrawal approval for Opana ER. Endo then agreed to withdrawal Opana ER from the market.

42. Earlier this month, as part of the bellwether litigation in MDL 2804, Endo agreed to pay the Ohio counties of Cuyahoga and Summit $10 million to settle the counties' lawsuits alleging that the company's false and unlawful marketing of opioids was responsible for the opioid epidemic in their respective communities.

d. Actavis

43. ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTAVIS PLC acquired ALLERGAN PLC in

[21] *Id.* at ¶ 23.
[22] *Id.* at ¶ 30.
[23] *Id.* at ¶ 41.

March 2015, and the combined company changed its name to Allergan PLC in January 2013. Before that, WATSON PHARMACEUTICALS, INC. acquired ACTAVIS, INC. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis PLC in October 2013. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by Allergan PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan PLC exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. Allergan PLC, Actavis PLC; Actavis, Inc.; Actavis LLC; Actavis Pharma, Inc.; Watson Pharmaceuticals, Inc.; Watson Pharma, Inc.; and Watson Laboratories, Inc. are referred to as "Actavis."

44. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the United States. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

45. Earlier this month, as part of the bellwether litigation in MDL 2804, Actavis agreed to pay the Ohio counties of Cuyahoga and Summit $5 million to settle the counties' lawsuits alleging that the company's false and unlawful marketing of opioids was responsible for the opioid epidemic in their respective communities.

e. Mallinckrodt

46. MALLINCKRODT, PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. MALLINCKRODT, LLC is a limited liability company organized and existing under the laws of the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, PLC. Over the years, Mallinckrodt LLC has been acquired by Avon, IMCERA, and finally Tyco, which eventually spun off its healthcare arm as Covidien. In 2013, Mallinckrodt began publicly trading as Mallinckrodt PLC. SpecGx LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly-owned subsidiary of Mallinckrodt PLC.

47. Mallinckrodt, PLC, SpecGx LLC, Avon, IMCERA, Tyco, Covidien, and Mallinckrodt, LLC are referred to as "Mallinckrodt." Mallinckrodt manufactures, markets, and sells in Allentown and throughout the United States drugs including generic oxycodone, of which it is one of the largest manufacturers.

48. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received approximately 25% of the DEA's entire annual quota for controlled substances that it manufactures. Mallinckrodt also estimated, based on IMS Health data for the same period, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.

49. In addition to generic opioids such as oxycodone, oxymorphone, hydromorphone, hydrocodone, and fentanyl, Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. The

FDA approved Exalgo for treatment of chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt has since discontinued. Mallinckrodt promoted its branded opioid products with its own direct sales force.

50. In July 2017 Mallinckrodt agreed to pay $35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the U.S. Drug Enforcement Agency ("DEA") of suspicious orders of controlled substances, including opioids, as required by law.[24] As part of the settlement, described more fully herein, Mallinckrodt agreed that it had failed to meet federal standards to maintain effective controls against the unlawful diversion of such dangerous substances.[25]

f. Marketing Conspirators Not Named as Defendants

51. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a subsidiary of Johnson & Johnson (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Janssen Pharmaceuticals, Inc. is formerly known as Ortho-McNeill-Janssen Pharmaceuticals, Inc., which in turn is formerly known as Janssen Pharmaceutica Inc.

52. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon information and belief,

[24] *See* Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

[25] Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC (July 10, 2017), https://www.justice.gov/usao-edmi/press-release/file/986026/download. ("2017 Mallinckrodt MOA").

J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit.

53. Noramco, Inc. ("Noramco") is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016.

54. Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., Noramco, and J&J are collectively referred to herein as "Janssen."

55. Janssen manufactures, promotes, sells, and distributes opioids in the United States, including the fentanyl-based Duragesic. Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta (tapentadol) and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

56. This week, Oklahoma state court Judge Thad Balkman ordered Johnson & Johnson to pay the state of Oklahoma $572 million in damages for promulgating "false, misleading, and dangerous marketing campaigns" that had substantially contributed to a public nuisance of opioid addiction and overdoses.[26]

57. Insys Therapeutics, Inc. ("Insys") is a publicly-traded company incorporated in the State of Delaware with its principal place of business in Chandler, Arizona.

58. Insys has marketed, sold, and distributed Subsys, an opioid-fentanyl drug that is approximately fifty times stronger than heroin and one hundred times more potent than morphine.

59. Insys has derived its revenue almost entirely from Subsys. According to its Form 10-K for the year ending December 31, 2015, Insys reported revenues of $331 million. Of that

[26] https://www.nytimes.com/2019/08/26/health/oklahoma-opioids-johnson-and-johnson.html

total, $329.5 million was derived from sales of Subsys.

60. Subsys is indicated "for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and are tolerant to opioid therapy for their underlying persistent cancer pain." [27] The indication also specifies that "SUBSYS is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain." In addition, the indication provides that "[p]atients must remain on around-the-clock opioids when taking SUBSYS." But according to a 2014 article in The New York Times, only 1% of prescriptions for Subsys were written by oncologists. Approximately half the prescriptions were written by pain specialists, with others written by other specialists including dentists and podiatrists.[28]

61. In August 2016, Insys agreed to pay $4.45 million to resolve a 2016 lawsuit filed by the Attorney General for the state of Illinois, alleging the company deceptively marketed its fentanyl-based painkiller Subsys.[29]

62. To date, at least two dozen Insys-connected individuals, including high-ranking Insys executives and corporate officials, sales representatives, and prescribers, have been indicted on, convicted of, and/or pleaded guilty to several serious criminal offenses in connection with the sale of Subsys through fraudulent and otherwise illegal methods.

63. Following a wave of indictments, Insys reluctantly acknowledged "certain mistakes and unacceptable actions of former Insys employees," claiming that those actions are

[27] The indication provides that "[p]atients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid daily for a week or longer."
[28] Katie Thomas, *Doubts Raised About Off-Label Use of Subsys, a Strong Painkiller*, N.Y. Times (May 13, 2014), https://www.nytimes.com/2014/05/14/business/doubts-raised-about-off-label-use-of-subsys-a-strong-painkiller.html.
[29] http://www.illinoisattorneygeneral.gov/pressroom/2017_08/20170818.html.

"not indicative of the people that are currently employed at Insys" and pointing to the fact that" over 90% of the 250 field-based sales staff employed prior to 2014 are no longer with the organization." According to the Attorney General for the State of New Jersey, however, the company remained comprised of such individuals at the time it made this claim.[30]

64. In June 2019, as part of a negotiated settlement with the U.S. Department of Justice, Insys admitted to bribing doctors to prescribe Subsys and agreed to pay the government $225 million. Within days, Insys filed for Chapter 11 bankruptcy.

65. Collectively, Purdue, Actavis, Cephalon, Janssen, Endo, Insys, and Mallinckrodt are referred to as "Marketing Conspirators."[31] Although not named as defendants in this Complaint, Janssen and Insys have coordinated with the defendants in the unlawful conduct, including racketeering offenses, described throughout this Complaint.

2. Distributor Defendants

66. At all relevant times, the Distributor Defendants (as defined below) have distributed, supplied, sold, and placed into the stream of commerce prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with federal and/or state law. The Distributor Defendants are engaged in "wholesale distribution," as defined under state and federal law. Plaintiff alleges the unlawful conduct by the Distributor Defendants is responsible for the volume of prescription opioids plaguing the Plaintiff's Community generally and the City specifically.

67. McKESSON CORPORATION ("McKesson") at all relevant times, operated as a

[30] New Jersey Attorney General Amended Complaint Against Insys, ¶¶242-47.
[31] Together, Purdue, Cephalon, Endo, and Mallinckrodt are also sometimes referred to as "RICO Marketing Defendants."

licensed pharmacy wholesaler in Pennsylvania. McKesson is a Delaware corporation. McKesson has its principal place of business located in San Francisco, California.

68. CARDINAL HEALTH, INC. ("Cardinal Health") at all relevant times, operated as a licensed pharmacy wholesaler in Pennsylvania. Cardinal Health's principal office is located in Dublin, Ohio. Based on Cardinal Health's own estimates, one of every six pharmaceutical products dispensed to United States patients travels through the Cardinal Health network

69. AMERISOURCEBERGEN DRUG CORPORATION ("AmerisourceBergen") at all relevant times, operated as a licensed pharmacy wholesaler in Pennsylvania. AmerisourceBergen is a Delaware corporation and its principal place of business is located in Chesterbrook, Pennsylvania.

70. McKesson, Cardinal Health, and AmerisourceBergen are collectively referred to as the Distributor Defendants.

71. The DEA's maintains in its confidential ARCOS database certain data (the "ARCOS data") about opioid distribution which was recently made available to the public (and the City) by order of Judge Dan A. Polster of the United States District Court for the Northern District of Ohio, where Judge Polster is presiding over coordinated proceedings in MDL 2804.

72. According to the ARCOS data, between 2006 and 2012 alone, well over 50 million prescription opioids were shipped to Lehigh County, which had fewer than 350,000 residents. Each year, therefore, the opioid industry was shipping enough prescription opioids to give every man, woman, and child in Lehigh County a three-week supply of opioids.

73. Each of the Distributor Defendants, which dominate 85% of the market share for the distribution of prescription opioids, shipped millions of prescription opioids into Lehigh County during this time period. Cardinal Health, for example, shipped over 15 million

prescription opioids into Lehigh County during that time.

74. As further detailed herein, each of the Distributor Defendants has been investigated and/or fined by the DEA for the failure to report suspicious orders. Plaintiff names each of the Distributor Defendants herein as defendants and places the industry on notice that Plaintiff is acting to abate the public nuisance plaguing the community.

C. Agency and Authority

75. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with Defendants' actual, apparent, and/or ostensible authority.

III. Jurisdiction & Venue

76. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 because the federal claims asserted herein, including claims asserted under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq.* and the federal Controlled Substances Act, raise a federal question. This Court has supplemental jurisdiction over Plaintiff's state-law claims under 28 U.S.C. § 1367 because those claims are so related to the federal claims as to form part of the same case or controversy.

77. This Court has personal jurisdiction over all Defendants because they (a) are registered to do business in this Commonwealth, (b) have their principal places of business or are otherwise located in this Commonwealth, (c) are transacting business in this Commonwealth, as defined by 42 Pa. C.S.A. §5322(a)(1), (d) are causing harm to Pennsylvania citizens by acts occurring outside the Commonwealth, 42 Pa. C.S.A. §5322(a)(4), and/or (e) have maintained

minimum contacts with this Commonwealth allowed under the United States Constitution, 42 Pa. C.S.A. §5322(b).

78. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b)(2) in that a substantial part of the events or omissions giving rise to the claim occurred in the Eastern District of Pennsylvania. Venue is also proper under 18 U.S.C. § 1965(a) because Defendants reside, are found, have agents, or transact their affairs in this district.

IV. The Public Health and Safety Crisis Caused by the Opioid Epidemic

A. The National Opioid Epidemic

79. The United States is suffering from an epidemic of addiction to opioids that continues to expand at an alarming rate. It is now the worst drug epidemic in our nation's history.

80. In the public health community, an epidemic is defined as a sharp increase in the prevalence of a disease (or diseases) within a discreet period of time.[32] The principal disease associated with the opioid epidemic is opioid addiction, also known as "opioid use disorder" or "opioid abuse or dependence." These all refer to, essentially, a "problematic pattern of opioid use leading to clinically significant impairment or distress … manifested by specific criteria such as unsuccessful efforts to cut down or control use, and use resulting in social problems and as a failure to fulfill major role obligations at work, school, or home."[33]

[32] *Principles of Epidemiology in Public Health Practice, Third Edition: An Introduction to Applied Epidemiology and Biostatistics (2017), available at* https://www.cdc.gov/ophss/csels/dsepd/ss1978/lesson1/section11.html.
[33] *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016* (March 18, 2016) (hereinafter "*CDC Guideline*, March 18, 2016"), *available at* https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf at pg. 2, *supra* note 8. The current diagnostic manual used by most behavioral health professionals, DSM-V, uses the term "opioid use disorder" to refer to and define what has in the past essentially been referred to as opioid addiction. In this Complaint, Plaintiff will generally use the term "addiction" to refer to opioid use disorder, opioid addiction, and opioid abuse or dependence, unless context dictates otherwise. These diagnoses are "different from tolerance (diminished response to a drug with repeated use) and physical dependence (adaptation to a drug that produces symptoms of withdrawal when the drug is stopped)." *Id.*

81. In 2011, the U.S. Centers for Disease Control and Prevention ("CDC") found a 900% increase in opioid users seeking treatment for opioid addiction in the period 1999-2010.[34] The sharp increase in opioid addiction during this period has also led to a sharp increase in opioid-related morbidity and mortality, including a disturbing increase in non-fatal and fatal opioid overdoses and other opioid-related adverse health effects.[35]

82. It was estimated that approximately 2.6 million Americans over the age of 12 were addicted to prescription pain relievers and heroin in 2015.[36] That number is likely even higher today.

83. According to the CDC, opioid addiction has led to an epidemic in opioid overdoses including overdose fatalities. In the period 1999-2014, the CDC estimated that there were 165,000 overdose deaths in the United States associated with prescription opioid use.[37] In the same period, an estimated 5 million non-fatal opioid overdoses were also likely to have occurred.[38]

84. Today, drug overdoses are the leading cause of death for Americans under age 50. More than 47,000 Americans died of opioid-related overdoses in 2017.[39]

85. Experts predict that opioids could kill 500,000 Americans over the next decade, and that the annual death toll will increase by at least 35 percent between 2015 and 2027—that

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[34] *CDC Vital Signs* (Nov. 2011) (hereinafter "*CDC Vital Signs*, Nov. 2011"), *available at* https://www.cdc.gov/vitalsigns/painkilleroverdoses/index.html; *accord* Andrew Kolodny *et al.*, *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, at pg. 560 (Jan. 12, 2015) (hereinafter "Kolodny, Jan. 12, 2015"), *available at* http://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-031914-122957.

[35] Morbidity relates to the incidence or prevalence of diseases and mortality relates to death resulting from those diseases.

[36] https://www.statnews.com/2017/06/27/opioid-deaths-forecast/ (last visited Aug. 13, 2019).

[37] *CDC Guideline*, March 18, 2016, at pg. 2, 18, *supra* note 8.

[38] This is based on health authorities' estimate that, for every opioid overdose death, there are 30 non-fatal overdoses.

[39] Center for Disease Control and Prevention, Drug Overdose Death Data, https://www.cdc.gov/drugoverdose/data/statedeaths.html (last visited Aug. 13, 2019).

means more than 93,000 deaths a year by 2027.[40]

86. Those who have an opioid dependency, but cannot obtain a prescription (either because they cannot afford it, or cannot find a doctor to fill it), increasingly turn from prescription pills to black market drugs like heroin or fentanyl – which are less expensive, often more accessible, and can be even more potent.[41] Indeed, 75 percent of patients in heroin treatment centers started their opioid use with prescription medications, not heroin.[42]

87. The increase in opioid prescriptions over the last two decades directly caused the corresponding rise of opioid addiction and related morbidity and mortality. In 1991, doctors wrote 76 million opioid prescriptions.[43] Less than a decade later, that number had almost doubled, jumping to 131 million.[44] By 2012, the number had nearly doubled again, to over 255 million prescriptions -- enough to provide a bottle of opioid pills to every American over the age of 14 that year.[45]

88. The national prescription opioid epidemic has created a public nuisance in communities like Allentown, where the costs are shared by individuals who have never taken opioids. Infants are born addicted to opioids. Children have lost parents. Adults have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used,

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[40] Max Blau, *STAT Forecast: Opioids could kill nearly 500,000 Americans in the next decade* (June 27, 2017), https://www.statnews.com/2017/06/27/opioid-deaths-forecast/ (last visited Aug. 13, 2019).
[41] *Id*.
[42] Maia Szalavitz, "Five Myths About Heroin" (March 4, 2016), https://www.washingtonpost.com/opinions/five-myths-about-heroin/2016/03/04/c5609b0e-d500-11e5-b195-2e29a4e13425_story.html?utm_term=.40eeb3df6d96 (last visited Aug. 13, 2019).
[43] *Id*.
[44] Christopher M. Jones, "*Prescription Drug Abuse & Overdose in the United States*" https://secure.in.gov/attorneygeneral/files/Jones_Indiana_RX_Meeting_-_CJONES(5).pdf (last visited Aug. 13, 2019).
[45] *Opioid Painkiller Prescribing*, Centers for Disease Control and Prevention: Vital Signs (July 2014), https://www.cdc.gov/vitalsigns/opioid-prescribing/.

abused, become addicted to, overdosed on, or been killed by opioids. Employers have lost healthy and productive workers. Patients are paying more for health care while health care providers suffer economic losses for increased costs. Illegal drug-dealing and drug-related crimes have depleted court and law enforcement resources and made neighborhoods less safe. Addicts using and seeking opioids have overtaken parks, libraries and other spaces meant for public use. By any metric, the opioid epidemic has been detrimental to Americans' quality of life.

89. The cost of the opioid epidemic is estimated to have exceeded $1 trillion from 2001 to 2017 and is projected to cost an additional $500 billion by 2020.[46]

90. The increased sales of prescription opioids are not accompanied by an overall change in the amount of pain reported, nor is the corresponding rise in addictions due to a medical breakthrough.[47]

91. Rather, the national opioid epidemic has been driven by the Defendants' determination to profit from American suffering. As a result of their deception, fraud and negligence, they have been richly, albeit unjustly, rewarded by the unprecedented increases in opioid prescriptions and addiction.

92. In the next hour, five Americans will fatally overdose from opioids;[48] two opioid

[46] *Economic Toll of Opioid Crisis In U.S. Exceeded $1 Trillion Since 2001*, https://altarum.org/about/news-and-events/economic-toll-of-opioid-crisis-in-u-s-exceeded-1-trillion-since-2001 (last visited Aug. 13, 2019). See also Esme Deprez. *The Lawyer Who Beat Big Tobacco Takes on the Opioid Industry*, Bloomberg Businessweek (Oct. 5, 2017), *available at* http://www.bloomberg.com/news/features/2017-10-05/the-lawyer-who-beat-big-tobacco-takes-on-the-opioid-industry (opioid epidemic cost the U.S. economy $78.5 billion in 2013, according to the U.S. Centers for Disease Control and Prevention, a quarter of which was paid by taxpayers through increased public costs for health care, criminal justice, and treatment).

[47] *See Overdoses of Prescription Opioid Pain Relievers United States, 1999—2008*, Centers for Disease Control and Prevention: Vital Signs (November 4, 2011), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm; *see also*, Chang H, Daubresse M, Kruszewski S, et al. *Prevalence and treatment of pain in emergency departments in the United States, 2000 – 2010*. Amer. J. of Emergency Med. 2014; 32(5): 421-31.

[48] Center for Disease Control and Prevention, Drug Overdose Death Data, https://www.cdc.gov/drugoverdose/data/statedeaths.html (last visited Aug. 13, 2019).

dependent babies will be born;[49] and a significant number of opioid addicts will switch from prescription opioids to heroin.[50]

93. During that same time period, opioid drug manufacturers will earn approximately $2.7 million from opioids as distributors continue to saturate communities like Allentown with these drugs.[51]

B. Prescription Opioids Have Driven this Epidemic

1. The Adverse Health Effects of Prescription Opioids

94. For millennia, opium has been recognized as a powerful, addictive and dangerous pain killer that provides human beings with intense feelings of euphoria when they consume the drug and agonizing symptoms when they withdraw.

95. Scientists have manufactured many derivatives of opium, including heroin, morphine and an array of prescription opioids, including brand-named drugs like OxyContin and Percocet and generics like oxycodone and hydrocodone. These prescription opioids are derived from or possess properties similar to opium and heroin, and pose the same dangers, including hazardous side effects and a high potential for abuse and addiction. Accordingly, they are regulated as controlled substances.[52]

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[49] Jean Y. Ko, PhD, *et al.*, Public Health Burden of Neonatal Abstinence Syndrome (March 10, 2017), https://www.cdc.gov/mmwr/volumes/66/wr/mm6609a2.htm (last visited Aug. 13, 2019).

[50] Patrick Keefe, *The Family that Built an Empire of Pain*, New Yorker (Oct. 23, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain (hereinafter "Keefe, *Empire of Pain*").

[51] Dina Gusovsky, "American Consume Vast Majority of World's Opioids, CNBC (April 27, 2016), https://www.cnbc.com/2016/04/27/americans-consume-almost-all-of-the-global-opioidsupply.html.

[52] Since passage of the Controlled Substances Act ("CSA") in 1970, opioids have been regulated as controlled substances. Controlled substances are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the highest. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. 21 U.S.C. § 812. Schedule II drugs may not be dispensed without an original copy of a manually signed prescription, which may not be refilled, from a doctor and filled by a pharmacist who both must be licensed by their state and registered with the DEA. 21 U.S.C. §

96. Prescription opioids work by binding to receptors on the spinal cord and in the brain, altering the perception of pain. Long-term exposure to opioids results in structural and functional changes in regions of the brain that regulate impulse control. Opioid addiction is a medical disease that arises from repeated exposure to opioids. It can occur in individuals using prescription opioids to relieve pain under the supervision of a physician at prescribed doses, just as it can occur in individuals using opioids for non-medical purposes.

97. Prescription opioids are highly addictive based on a dual risk: (i) they induce euphoria (positive reinforcement), and (ii) cessation of chronic opioid use produces dysphoria (negative reinforcement) or withdrawal.[53]

98. Discontinuing opioid use, even after just a few days of therapy, can cause patients to experience withdrawal symptoms. Withdrawal symptoms can include anxiety, nausea, vomiting, agitation, insomnia, muscle aches, abdominal cramping, and other serious conditions, which may persist for months or longer after a complete withdrawal from opioids, depending on how long the opioids were used.[54]

99. When opioids are used over time, patients grow tolerant to their analgesic and euphoric effects. As tolerance increases, a patient requires progressively higher doses in order to

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829. Opioids that have been categorized as Schedule II drugs include morphine (Avinza, Embeda, Kadian, MS Contin), fentanyl (Duragesic, Actiq, Fentora), methadone, oxycodone (OxyContin, Percocet, Percodan, Tylox), oxymorphone (Opana), and hydromorphone (Dilaudid, Palladone).

Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence. 21 U.S.C. § 812. Schedule III drugs may not be dispensed without a written or oral prescription, which may not be filled or refilled more than six months after the date of the prescription or be refilled more than five times. 21 U.S.C. § 829. Some opioids had been categorized as Schedule III drugs, including forms of hydrocodone and codeine combined with other drugs, like acetaminophen. However, in October 2013, the FDA, following the recommendation of its advisory panel, reclassified all medications that contain hydrocodone from Schedule III to Schedule II.

[53] Roy Wise *et al.*, *The Development and Maintenance of Drug Addiction*, Neuropsychopharmacology (Nov. 6, 2013), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3870778/.

[54] *See, e.g.*, *Health Guide: Opiate Withdrawal*, The New York Times (2013), *available at* http://www.nytimes.com/health/guides/disease/opiate-withdrawal/overview.html?mcubz=3.

obtain the same levels of pain reduction to which he or she become accustomed.[55] At higher doses, the effects of withdrawal are more substantial, leaving a patient at an even higher risk of addiction.

100. Opioids can slow breathing and cause severe respiratory depression, coma, or death. These hazards can occur even when used at prescribed doses, and can affect (sometimes fatally) even users who are not suffering from opioid addiction or opioid use disorder.

101. Prior to the marketing campaign that the Marketing Conspirators launched (and the Distributor Defendants were enriched by), physicians avoided using opioids for long-term treatment of chronic pain. Clinicians observed various negative outcomes from long-term opioid therapy: a mixed record in reducing long-term pain; failure to improve patient function; greater pain complaints over time as most patients developed tolerance to opioids; diminished ability to perform basic tasks; inability to make use of complementary treatments like physical therapy due to opioid side effects; and opioid addiction.

102. Up to the mid-1990s, the medical profession viewed opioids as having legitimate uses, but believed that they should be prescribed cautiously and only on a limited basis because of concerns about addiction, tolerance leading to dose escalation, and physiological dependence resulting in difficulty discontinuing use. Physicians were reluctant to prescribe opioids on a long-term basis for common chronic pain conditions because of their addiction risks and side effects.[56]

103. In the late 1990s, the rate of prescription opioid use began accelerating rapidly. This acceleration was directly related to, and coincided with, efforts of the Marketing

[55] M. Katz, *Long-Term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith*, 170(16) Archives of Internal Med. 1422 (2010).
[56] Kolodny, Jan. 12, 2015 at pg. 562.

Conspirators to deceptively promote the benefits of long-term prescription opioid use and minimize the risks of prescription opioids, discussed more fully below.

2. The Lack of Scientific Evidence to Support Prescription Opioids for Long-Term Use

104. Scientific evidence has not demonstrated the safety of prescription opioids for long-term daily use to treat chronic pain nor is there substantial evidence that these dangerous drugs improve functioning to a degree that would justify their substantial risks.

105. As a result of the widespread, unsupported use of prescription opioids for long-term chronic pain, the U.S. Centers for Disease Control and Prevention ("CDC") developed the "CDC Guideline for Prescribing Opioids for Chronic Pain" in March 2016 (the "2016 CDC Guideline," "CDC Guideline," or "Guideline").[57] The 2016 CDC Guideline extensively discussed the evidence (and lack thereof) supporting opioid use to treat long-term chronic pain.

106. Chronic pain generally refers to pain lasting three months or longer. In the 2016 CDC Guideline, the CDC stated: "Chronic pain has been variably defined but is defined within this [opioid treatment] guideline as pain that typically lasts >3 months or past the time of normal tissue healing. Chronic pain can be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or an unknown cause."[58]

107. As indicated by the CDC, there are no controlled studies of the use of opioids to treat chronic pain beyond 12 weeks, nor reliable evidence that opioids improve patients' pain and function long-term.[59]

108. Specifically, based on a detailed review of prior opioid studies, the CDC concluded that "evidence on long-term opioid therapy for chronic pain outside of end-of-life care

[57] *CDC Guideline*, March 18, 2016.
[58] *Id.* at pg. 1.
[59] *Id.* at pg. 2, 9.

remains limited, with *insufficient evidence to determine long-term benefits versus no opioid therapy*."[60] The CDC Guideline further stated: "No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later...."[61] The 2016 CDC Guideline also stated: "Extensive evidence shows the possible harms of opioids (including opioid use disorder, overdose, and motor vehicle injury)."[62]

109. As referred to in the 2016 CDC Guideline, the first randomized, placebo controlled studies appeared in the 1990s, and revealed evidence only for *short-term* efficacy of opioids, and only in a minority of patients.[63]

110. Subsequent reviews of the use of opioids for cancer and non-cancer pain consistently noted the lack of available data to assess long-term outcomes.

111. For example, a 2004 report reviewed 213 randomized, controlled trials of treatments for cancer pain and found that, while opioids had short-term efficacy, the data was insufficient to establish long-term effectiveness.[64]

112. A 2007 systematic review of opioids for back pain found that the evidence did not allow judgments regarding long-term use.[65]

113. Similarly, a 2011 systematic review of studies for non-cancer pain found that evidence of long-term efficacy was "poor."[66]

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[60] *Id.* at pg. 9 (emphasis added).
[61] *Id.* at pg. 15.
[62] *Id.* at pg. 15.
[63] Nathaniel Katz, *Opioids: After Thousands of Years, Still Getting to Know You*. 23(4) Clin. J. Pain 303 (2007); Roger Chou *et al.*, *Research Gaps on Use of Opioids for Chronic Noncancer Pain*, 10(2) J. Pain 147 (2009).
[64] Daniel Carr *et al.*, *Evidence Report on the Treatment of Pain in Cancer Patients*, Jnl. of the Nat'l. Cancer Institute Monographs No. 32 (2004), *available at* https://academic.oup.com/jncimono/article-lookup/doi/10.1093/jncimonographs/lgh012.
[65] BA Martell *et al.*, *Systematic Review: Opioid Treatment for Chronic Back Pain: Prevalence, Efficacy, and Association with Addiction*, Annals of Internal Medicine (2007), *available at* https://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0024176/.
[66] L. Manchikanti *et al.*, *A Systematic Review of Randomized Trials of Long-Term Opioid Management for Chronic Non-Cancer Pain*, Pain Physician (2011), *available at* https://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0032394/.

114. One year later, a similar review reported poor evidence of long-term efficacy for morphine, tramadol, and oxycodone, and only fair evidence for transdermal fentanyl (approved only for use for cancer pain).[67]

115. In 2015, a systematic review of the effectiveness and risks of long-term opioid therapy found that the "[e]vidence is insufficient to determine the effectiveness of long-term opioid therapy for improving chronic pain and function."[68]

116. Relatedly, substantial evidence indicates that opioid drugs actually *worsen* patients' health. While opioids may work sufficiently well in short term applications, long-term use very often leads to a decline in the patient's overall functionality, general health, mental health, and social function.

117. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in patients' functional outcomes over other non-addicting treatments.[69]

118. Studies have shown that increasing the duration of opioid use is strongly associated with an increasing prevalence of negative mental health conditions (including depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater utilization of health care services.

119. Over time, even high doses of opioids often fail to control pain due to tolerance

[67] D. Koyyalagunta *et al.*, *A Systematic Review of Randomized Trials on the Effectiveness of Opioids for Cancer Pain*, Pain Physician (2012), *available at* https://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0052579/.
[68] Roger Chou *et al.*, *The Effectiveness and Risks of Long-Term Opioid Therapy for Chronic Pain: A Systematic Review for a National Institutes of Health Pathways to Prevention Workshop*, Annals of Internal Medicine (Feb. 17, 2015), *available at* http://annals.org./aim/fullarticle/2089370/effectiveness-risks-long-term-opioid-therapy-chronic-pain-systematic-review.
[69] Andrea D. Furlan *et al.*, *Opioids for Chronic Noncancer Pain: a Meta-Analysis of Effectiveness and Side Effects*, 174(11) Can. Med. Ass'n J. 1589 (2006).

levels rising, and many patients exposed to such doses are unable to function normally.[70]

120. The lack of evidence to support the long-term use of prescription opioids is true for both general pain and scientific pain conditions. For example, studies of the use of opioids for chronic lower back pain have been unable to demonstrate an improvement in patients' function. Instead, research consistently shows that a long-term opioid therapy for patients who have lower back injuries does not cause patients to return to work or physical activity sooner: "Opioids do not seem to expedite return to work in injured workers or improve functional outcomes of acute back pain in primary care. For chronic back pain, systematic reviews find scant evidence of efficacy.... Given the brevity of randomized controlled trials, the long term effectiveness and safety of opioids are unknown."[71]

121. Similarly, as many as 30% of patients who suffer from migraines have been prescribed opioids to treat headaches. Users of opioids had the highest increase in the number of headache days per month, scored significantly worse on the Migraine Disability Assessment, and had higher rates of depression compared to non-opioid users.[72]

122. A survey by the National Headache Foundation found that migraine patients who used opioids were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other medications.[73]

3. Increases in Opioid Addiction and Opioid Deaths Coincide with

[70] Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Medicine (Fall 2009), *available at* http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse.aspx?pageid=144&tabid=747.
[71] Richard Deyo *et al.*, *Opioids for Low Back Pain*, BMJ Publishing (Jan. 5, 2015), *available at* http://www.bmj.com/content/350/bmj.g6380.
[72] Dawn C. Buse *et al.*, *Opioid Use and Dependence Among Persons With Migraine: Results of the AMPP Study*, Headache (Jan. 23, 2012), *available at* http://onlinelibrary.wiley.com/doi/10.1111/j.1526-4610.2011.02050.x/abstract;jsessionid=25D4FE8717B0D8C823D88F3DEA5983AC.f04t03.
[73] *Survey: Migraine Patients Taking Potentially Addictive Barbiturate or Opioid Medications Not Approved by FDA as Migraine Treatments* (May 15, 2017), *available at* https://www.thefreelibrary.com/Survey%3A+Migraine+Patients+Taking+Potentially+Addictive+Barbiturate+or+…-a0163389345.

Increased Use of Prescription Opioids for Medical Purposes

123. The alarming increase in opioid addiction and related deaths in the last 20 years has coincided with the correlating expansion of prescription opioid use for medical purposes. Between 1999 and 2010 alone, the sale of prescription opioids in the U.S. more than tripled.

124. In 2010 alone, 254 million prescription for opioids were filled in the United States – enough to medicate every adult in America around the clock for a month.[74] In 2010, 20% of all doctors' visits resulted in the prescription of an opioid.[75]

125. Americans constitute only 4.6% of the world's population yet consume 80% of the global opioid supply.[76]

126. According to a 2017 report commissioned by the City of Philadelphia, nearly 70% of adults nationwide had used opioid pain medication in their lifetimes, and approximately 30% had used opioids in the previous year.[77]

127. In 2012, 7% of adults aged 20 and over reported using a prescription opioid in the past 30 days.[78]

128. A recently published federal survey estimates that 92 million Americans received an opioid prescription in 2015.[79]

129. Prescription opioids, once a niche drug class, are now the most prescribed

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[74] *CDC Vital Signs*, Nov. 2011, *supra* note 28; Katherine Eban, *OxyContin: Purdue Pharma's Painful Medicine*, Forbes (Nov. 9, 2011), *available at* http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/.
[75] M. Daubresse, *et al.*, Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010, 51(10) Med. Care 870-78 (2013).
[76] *American Society of Interventional Pain Physicians (ASIPP) Fact Sheet*, at pg. 2, *available at* https://www.asipp.org/documents/ASIPPFactSheet101111.pdf.
[77] *See, e.g.*, *The Mayor's Task Force to Combat the Opioid Epidemic in Philadelphia: Final Report and Recommendations*, City of Philadelphia, at pg. 6 (May 19, 2017), *available at* http://dbhids.org/wp-content/uploads/2017/05/OTF_Report.pdf.
[78] https://www.cdc.gov/nchs/data/databriefs/db189.htm.
[79] Beth Han *et al.*, *Prescription Opioid Use, Misuse, and Use Disorders in U.S. Adults: 2015 National Survey on Drug Use and Health*, 167 (5) Annals of Internal Medicine 293-301 (2017), *available at* https://www.doh.wa.gov/Portals/1/Documents/2300/2017/AnnalsInternalMed.pdf.

therapeutic class of drugs in the U.S.

130. Only recently, as result of a growing awareness of the true risks of prescription opioids relative to their efficacy (if any) for long-term use, segments of the medical profession have begun to counter the Defendants' efforts to artificially inflate the numbers of prescriptions for opioids. In February 2017, for example, the "Veterans Affairs/Department of Defense Clinical Practice Guideline for Opioid Therapy for Chronic Pain" strongly recommended "against initiation of long-term opioid therapy for chronic pain."[80] But even if the overall prescription of opioids are reduced to appropriate levels, it will take years to address the devastation that has been wrought by the opioid epidemic.

4. Increases in Prescription Opioid Sales Are the Principal Cause of Increased Addiction Rates and Overdose Deaths

131. Over the past two decades, the rates of prescription opioid sales, opioid addiction, and opioid overdose deaths have risen together and closely track each other.

132. In 2017, the CDC noted that "[p]rescription opioid-related overdose deaths and admissions for treatment of opioid use disorder have increased in parallel with increases in opioids prescribed in the United States, which nearly quadrupled from 1999 to 2010."[81] Similarly, the CDC noted in 2016 that "[s]ales of opioid pain medication have increased in parallel with opioid-related overdose deaths."[82]

133. The direct correlation between increases in sales of prescription opioids and opioid addiction and overdoses prompted the CDC and other public health authorities to conclude that the principal cause of the epidemics of opioid addiction and overdoses in the

[80] *Veterans Affairs/Department of Defense Clinical Practice Guideline for Opioid Therapy for Chronic Pain* (February 2017), available at https://www.healthquality.va.gov/guidelines/Pain/cot/VADoDOTCPG022717.pdf.
[81] *Vital Signs: Changes in Opioid Prescribing in the United States, 2006-2015*, at pg. 1 (July 7, 2017), *available at* https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6626a4.pdf.
[82] *CDC Guideline*, March 18, 2016, at pg. 2, *supra* note 8.

period 1999-2014 was the unprecedented increase in use of prescription opioids.[83] The CDC gathered data relating to prescription opioid usage using sales of prescription opioids as a measure of prescription opioid usage, and correlated these data with data relating to admissions for treatment of opioid use disorders and overdose deaths.

134. Research shows that sharp, dramatic increases in the sale of prescription opioids for medical purposes closely track sharp, substantial increases in addiction as measured by treatment admissions (as previously described) and fatal overdose.[84]

135. The CDC and other researchers have concluded that prescription opioid usage for daily use to treat chronic pain has been the principal causative factor driving the epidemics of opioid addiction and overdoses.[85]

136. Public health authorities have also concluded that prescription opioid use is responsible not only for the addiction and overdose epidemics relating directly to prescription opioids, but also for the multi-year surge in non-prescription, illegal opioid use, including the use of heroin. Apparently, as law enforcement and public health authorities and the medical profession have begun to limit the improper use of prescription opioids and for other reasons (including the high price of prescription opioids), which has reduced the supply of prescription opioids for legal use, many prescription opioids users suffering from opioid addiction have turned to heroin available on the black market.[86]

137. Based on the growing weight of scientific evidence, public health experts have concluded that the current opioid epidemics of addiction and overdoses have been caused

[83] *Id.* at pg. 2.
[84] Kolodny, Jan. 12, 2015, at pg. 560, *supra* note 7.
[85] *CDC Guideline*, March 18, 2016, at pg. 2, *supra* note 8.
[86] Approximately 80% of individuals who begin using heroin made the transition from initial prescription opioids. *See* Kolodny, Jan. 12, 2015, at pg. 560, *supra* note 7.

primarily by opioid pain relievers marketed and sold by opioid manufacturers and their agents and prescribed by the medical community for long-term daily use to treat chronic pain. Studies show that the over-prescription of opioid pain relievers accounts for the use of opioids by the vast majority of persons addicted to opioids and experiencing opioid overdoses.[87]

138. The CDC has concluded that unless and until the prescription of opioids by the medical community is reduced to appropriate levels, the current epidemics of opioid addiction and overdoses will not be contained.[88] Even then, it may take decades before the populations currently addicted as a result of the opioid epidemic are appropriately treated.

139. Chronic pain patients and others – from users to their loved ones and communities at large – have been devastated by the prescription and use of opioids for medical uses. Some estimates of long-term prescription opioid users developing addiction are frighteningly high: one study found that between 30% and 40% of all long-term users of opioids experience problems with opioid use disorders.[89]

5. Recognition of an Opioid "Epidemic," "Crisis," and "Public Health Emergency"

140. Killing more than 100 people every day,[90] the opioid epidemic has led to many more overdose deaths than the heroin epidemic of the 1970s and the crack cocaine epidemic of the 1980s and 1990s, prompting public health officials and commentators to conclude that the current opioid epidemic is the worst drug epidemic in U.S. history – worse than the previous

[87] Kolodny, Jan. 12, 2015, at pg. 563, *supra* note 7; *CDC Guideline*, March 18, 2016, at pg. 2, *supra* note 8.
[88] Kolodny, Jan. 12, 2015, *supra* note 7, at pg. 565; *CDC Guideline*, March 18, 2016, at pg. 2-3, *supra* note 8.
[89] J. Boscarino *et al.*, *Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria*, 30(3) Journal of Addictive Diseases 185 (2011); J. Boscarino *et al.*, *Risk Factors for Drug Dependence Among Outpatients on Opioid Therapy in a Large US Healthcare System*, 105(10) Addiction 1776 (2010).
[90] Center for Disease Control and Prevention, Drug Overdose Death Data, https://www.cdc.gov/drugoverdose/data/statedeaths.html (last visited Aug. 13, 2019).

heroin and crack cocaine epidemics combined.[91]

141. The CDC has acknowledged the presence of an "opioid epidemic," also referred to as an "opioid overdose epidemic."[92]

142. A 2017 report by the DEA noted that the "opioid overdose crisis … is a public health and public safety emergency."[93]

143. The U.S. Department of Health and Human Services recognized the existence of an "opioid crisis" and stated that the "United States is in the midst of a prescription opioid overdose epidemic."[94]

144. The U.S. Surgeon General noted in 2016 that opioid use had led to an "urgent health crisis" that specifically coincided with "*heavy marketing of opioids to doctors.*"[95]

145. Similarly, the National Institutes of Health identified the drug industry's "aggressive marketing" as a major cause of the opioid epidemic: "Several factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include drastic increases in the number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and *aggressive marketing by pharmaceutical companies.*"[96]

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[91] Andrew Kolodny, M.D., *Responding to the Prescription Opioid and Heroin Crisis: An Epidemic of Addiction*, at 4 (2016), *available at* http://www.pdmpassist.org/pdf/TTAC_Opioid_Policy_Research_Collaborative_20170726.pdf.

[92] *CDC Guideline*, March 18, 2016, at pg. 3, 34, *supra* note 8; *accord* CDC Press Release, Sept. 25, 2017 (recognizing "opioid epidemic"), *supra* note 32.

[93] *Analysis of Overdose Deaths in Pennsylvania, 2016*, Drug Enforcement Agency Philadelphia Division and the University of Pittsburgh, at pg. 5 (July 2017) (hereinafter "*Analysis of Overdose Deaths in Pennsylvania*, July 2017"), *available at* https://www.overdosefreepa.pitt.edu/wp-content/uploads/2017/07/DEA-Analysis-of-Overdose-Deaths-in-Pennsylvania-2016.pd_-1.pdf.

[94] *Opioids: The Prescription Drug & Heroin Overdose Epidemic*, U.S. Dept. of Health and Human Services (2017), *available at* https://www.hhs.gov/opioids.

ss[95] https://turhthetiderx.org/ (emphasis added).

[96] *America's Addiction to Opioids: Heroin and Prescription Drug Abuse* (2014) (emphasis added), *available at* https://www.drugabuse.gov/about-nida-legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse.

146. On October 26, 2017, the President of the United States declared a national "public health emergency" caused by opioid addiction.[97] This action allows for shifting of resources within certain government programs to help people eligible for those programs receive treatment for opioid addiction and opioid use disorder.[98]

147. On April 2, 2018, the U.S. Attorney General announced that the U.S. Department of Justice had moved to join the litigation in MDL 2804 as a friend of the Court, citing, *inter alia*, the "substantial economic burden" that the opioid epidemic had placed on the American people and their government.[99]

C. Pennsylvania's Opioid Epidemic

148. Pennsylvania has been especially ravaged by the national opioid crisis.

149. Pennsylvania is among the top four states with the highest opioid use and overdose rates.[100] Nearly *thirteen people die every day* from a drug overdose in the Commonwealth.[101] Drug-related fatalities in Pennsylvania now outnumber persons killed in car accidents and murders combined.[102]

150. The rate of drug-related overdose deaths in Pennsylvania far exceeds the national average.[103] According to recent studies, opioids killed an estimated 26,300 Pennsylvanians from

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[97] White House Office of the Press Secretary, *President Donald J. Trump is Taking Action on Drug Addiction and the Opioid Crisis* (Oct. 26, 2017), *available at* https://www.whitehouse.gov/the-press-office/2017/10/26/president-donald-j-trump-taking-action-drug-addiction-and-opioid-crisis; *see also* The President's Commission on Combating Drug Addiction and the Opioid Crisis (Nov. 1, 2017), *available at* https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.

[98] *Id.*

[99] *See* https://www.justice.gov/file/1048036/download.

[100] CDC/National Center for Injury Prevention and Control, https://www.cdc.gov/drugoverdose/data/statedeaths.html and https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state

[101] Pennsylvania Department of Drug and Alcohol Programs, https://data.pa.gov/stories/s/Rescue/dji6-fb2x

[102] CDC/National Center for Health Statistics, https://www.cdc.gov/nchs/pressroorn/sosmap/homicide_mortality/homicide.htm and Pennsylvania Department of Transportation, https://www.penndot.gov/TravellnPNSafety/Pages/Crash-Facts-and-Statistics.aspx

[103] Pennsylvania DEA Opioid Threat Report 2018, https://www.overdosefreepa.pitt.edu/wp-content/uploads/2018/10/PA-Opioid-Report-Final.pdf

1999 to 2017.[104] Pennsylvanians also survived more than 6,400 opioid overdoses from April 2015 through 2017. Though not fatal, these overdoses were still devastating.[105]

151. The opioid epidemic continues to ravage communities across the Commonwealth. For example, between 2015 and 2017, Pennsylvania coroners and medical examiners reported 13,408 drug-related overdose deaths-a 65% increase from previous years.[106] Over half of those deaths involved opioids of which nearly a quarter were prescribed.[107] Oxycodone is the most frequently reported prescription opioid in toxicology tests of drug-related overdose decedents occurring in Pennsylvania.[108]

152. Thousands of patients who took prescription opioids in Pennsylvania became addicted and died. Drug overdoses skyrocketed 81% in 2016 alone.[109] In 2017, Pennsylvania suffered more drug overdose deaths than any other state[110] and a majority of those deaths were caused by opioids.[111]

153. Despite these fatalities, opioid use in Pennsylvania remains one of the highest in the country. [112]

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[104] *Id*. *See also* Jeanine Buchanich et al., The effect of incomplete death certificates on estimates of unintentional opioid-related overdose deaths in the United States, 1999-2015, Public Health Rep. (2018), https://doi.org/10.l 177/0033354918774330; see also Kaiser Family Foundation analysis of CDC/National Center for Health Statistics (Multiple Cause of Death Files 1999- 2017), https://www.kff.org/state-category/health-status/opioids/

[105] Pennsylvania Department of Drug and Alcohol Programs, https://data.pa.gov/stories/s/Rescue/dji6-fb2x

[106] OverdoseFreePA, https://www.overdosefreepa.pitt.edu/know-the-facts/death-data-overview/; Pennsylvania DEA Opioid Threat Report 2018

[107] *Id*.

[108] Pennsylvania DEA Opioid Threat Report 2018

[109] Jessica Glenza, Opioid crisis: overdoses increased by a third across US in 14 months, says CDC, The Guardian (2018), https://www.theguardian.com/us-news/2018/mar/06/opioid-crisis- overdoses-increased-by-a-third-across-us-in-14-months-says-cdc.

[110] Erin Durkin, US drug overdose deaths rose to record 72,000 last year, data reveals, The Guardian (2018), https://www.theguardian.com/us-news/2018/aug/16/us-drug-overdose-deaths- opioids-fentanyl-cdc; Lenny Bernstein, Bloomberg Philanthropies will donate $50 million to battle opioid epidemic, The Washington Post (2018), https://www.washingtonpost.com/national/health-science/bloomberg-philanthropies-will-donate- 50-million-to-battle-opioid-epidemic/2018/11/29/14fccc5c-f3fb-11e8-80d0-f7el 948d55f4_story.html?utm_tenn=.363ebb1843b3

[111] Pennsylvania DEA Opioid Threat Report 2018

[112] *Id*.

154. As the number of opioid-related overdoses continues to rise in Pennsylvania and nationwide, the economic cost of the epidemic has skyrocketed in recent years. From health care spending to addiction treatment and from lost productivity to criminal justice expenses, the financial impact of these costs is staggering. Between 2012 and 2016, opioid-related fatalities in Pennsylvania cost taxpayers more than $142 billion dollars. These costs more than doubled from 2015 to 2016. [113] These figures reflect only four years of this much larger epidemic.

D. The Opioid Epidemic in Allentown and the Lehigh Valley

1. The Impact on Public Health, Public Safety and Quality of Life

155. The national opioid epidemic has ravaged Allentown along with other areas in and around Plaintiff's Community, including but not limited to surrounding areas in Lehigh, Northampton, and Berks Counties. The widespread opioid abuse, addiction, morbidity, and mortality have resulted in an ongoing public nuisance in Allentown.

156. In Lehigh County alone, 308 people died of drug overdoses between 2016 and 2017, with most of those deaths being related to opioids.[114] More than a third of these people died within the city limits of Allentown.

157. Excluding deaths that occurred at hospitals, 65 Allentown residents died of an overdose last year. The death toll from the year before was 72.

158. Opioid abuse is a threat to the health of not only those who have used opioids, but even Allentown residents who have not.

159. For example, opioid use during pregnancy can lead to neonatal abstinence syndrome (NAS) and interfere with a child's brain development, resulting in subsequent

[113] Report from the U.S. Senate Committee on Health, Education, Labor, and Pensions: *The Economic Cost of the Opioid Epidemic in Pennsylvania*, https://www.overdosefreepa.pitt.edu/wp-content/uploads/2018/ I0/The-Economic-Cost-of-the- Opioid-Epidemic-in-Pennsylvania.pdf

[114] https://www.dea.gov/sites/default/files/2018-10/Opioid%20threat%20in%20Pennsylvania%20FINAL.pdf

consequences for mental functioning and behavior. In the last two years for which data is available for all maternal hospital stays involving substance use, almost half of these hospitalizations involved opioids.[115] Lehigh County was in the top 25% of the Pennsylvania counties with the most recorded maternal stays involving opioid use.[116]

160. According to the CDC, an increase in infectious diseases such as the Hepatitis C virus (HCV) in the United States is directly tied to intravenous injection of opioids. Allentown is no exception to this trend. According to Allentown's Bureau of Health, roughly eight out of ten Allentown residents diagnosed with HCV identify past or current IV drug use as a risk factor.

161. The opioid epidemic is a growing threat to not only the City's public health but also its public safety, as a result of the dramatic increase in opioid-related crimes. Such crimes include theft of money or property to finance opioid addiction; theft of prescription opioids from friends, relatives or others; and crimes committed while under the influence of opioids. Opioid abuse has adversely impacted neighborhood public safety and well-being in the City.

162. For example, opioid addiction has led to an alarming number of "strong arm robberies" in Allentown, with more than 1,500 such robberies in the last 10 years alone. An increasing percentage of these crimes are committed by robbers who are desperate for money to feed an opioid addiction. In addition to harming the intended victims of these robberies and taxing the resources of the Allentown Police Department and other city resources, this spate of robberies has caused the public to fear for its safety, health, and welfare.

2. The Opioid Epidemic Has Greatly Impacted the City's Budget

163. The City's efforts to address and abate these opioid related harms have come at

[115] Pennsylvania Health Care Cost Council, http://www.phc4.org/reports/researchbriefs/opioids/121118/docs/researchbrief_opioids121118.pdf.
[116] *Id*.

considerable cost. Financial burdens to the City have expanded along with the increased sale, use, and misuse of opioids in the City.

164. With an annual budget of over $100 million, the City provides services to protect public health and safety through departments such as EMS, and Allentown's Police Department and Bureau of Health.

165. These City services have been severely burdened by the opioid epidemic at substantial increased costs to the City including, without limitation, increased training costs, costs for required personnel, and increased costs for EMS services.

166. The City's first responders have been required to expend considerable City resources—often at great personal risk—in addressing the most severe harms associated with opioid addiction.

167. EMS, for example, has responded to thousands of emergency calls to rescue those suffering from the effects of opioid abuse. Although EMS bills patients for its services, its paramedics must provide care without regard to a patient's ability to pay. Consequently, the uncompensated care costs associated with treating opioid overdoses has ballooned.

168. Since 2010 alone, EMS has provided nearly $6 million worth of emergency services after responding to emergency calls for patients believed to be suffering from the effects of drug abuse. But the City has only been paid for a fraction of the billed services, resulting in losses of over $4 million in just the last 9 years.

169. The vast majority of these calls – and the cause of their increasing numbers –are largely driven by opioid overdoses.

170. During this time period, the number of opioid related calls for service handled by Allentown's EMS has increased 1700%.

171. The costs associated with EMS rescues reflect only a portion of the City's expenditures on emergency treatment. For example, Allentown police officers are increasingly resuscitating overdose victims with Narcan. As a result, Lehigh County ranked among the top five counties in Pennsylvania for naloxone administrations by law enforcement agencies in 2017.[117]

172. While saving lives and reducing harms associated with the opioid epidemic, first responders are often at great personal risk. In just the last four years, Allentown police officers have suffered dozens of injuries in the course of drug-related encounters, requiring treatment, testing, and time away from work. Of the instances where the nature of the narcotics was determined, more than a third involved opioids.

173. The opioid epidemic has forced the Allentown Police Department and other City departments to divert resources towards City/County initiatives such as the Blue Guardian program, in which Allentown police officers and County social workers team up to help survivors of opioid overdoses. While this effort has saved lives by helping get people into recovery, it has cost the City hundreds of thousands of dollars in manpower, training and other costs while depleting resources needed to combat other dangers to the people of the Allentown, including an alarming level of gun violence.

174. Similarly, the resources of Allentown's Bureau of Health (which receives approximately half of its annual $5 million budget from the City) have been strained by the opioid epidemic.

175. At present, more than two-thirds of the Bureau of Health's personnel are actively

[117] https://www.dea.gov/sites/default/files/2018-10/Opioid%20threat%20in%20Pennsylvania%20FINAL.pdf, at 46-47.

addressing the devastation caused by the opioid epidemic, including not only opioid addiction but also secondary causes such as sexually transmitted infections and other infectious diseases caused by intravenous opioid use.

176. The Bureau, which runs both a Sexually Transmitted Disease clinic and an HIV testing clinic, provides testing, treatment and surveillance/monitoring of thousands of people who live in, work in, and/or frequent Allentown. Last year, the Bureau received 1,886 new reports of sexually transmitted infections of Allentown residents, requiring additional surveillance and/or treatment.

177. At all times material hereto, the City has provided health, dental and life insurance benefits to its employees and their family members, through a self-funded plan. This plan has included coverage for prescription drugs and pharmacy plans. The City has largely or fully subsidized these plans for its employees and their family during these times.

178. The City's costs for these employee and family benefits has been exorbitant, in part because of the costs related to (1) visits to doctor's offices when covered employees and their family members visit doctors to obtain opioid prescriptions; (2) opioid addiction treatment for covered employees and their family members; (3) treatment for infectious diseases attributable to opioid use, and; (4) medical care needed to treat opioid side effects, or the increases in the rates of coverage nationally because of these general increases in costs and services due to the opioid epidemic, caused by Defendants.

179. In Allentown, like other parts of the country, long-term opioid use has led to longer worker's compensation claim duration, long-term disability leaves, higher costs, and higher medical expenses. The City has suffered increases in lost employee time related to opioid use.

THE UNLAWFUL DECEPTIONS OF THE MARKETING CONSPIRATORS

V. The Marketing Conspirators' Wrongful Conduct Created the Public Health and Safety Crisis and was False and Deceptive

180. It is well established that marketing can and does impact prescribing habits of physicians and practices of third-party payors, health plan administrators and others.[118]

181. The Marketing Conspirators improperly marketed opioids for years using false, misleading and deceptive messages that overstated and/or misrepresented the safety and efficiency of opioids and understated the risk of those drugs.

A. Purdue Sought to Change the Practices of Prescribers

182. Given the history of opioid abuse in the U.S. and the medical profession's resulting wariness, the commercial success of the Marketing Conspirators' prescription opioids would not have been possible without a fundamental shift in prescribers' perception of the risks and benefits of long-term opioid use.

183. As it turned out, Purdue was uniquely positioned to execute just such a maneuver, thanks to the legacy of a man named Arthur Sackler. The Sackler family is the sole owner of Purdue and one of the wealthiest families in America, with a net worth of $13 billion as of 2016. The company's profits go to Sackler family trusts and other entities. Yet the Sacklers have avoided publicly associating themselves with Purdue, letting others serve as the spokespeople for the company.

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[118] *See, e.g.,* Ian Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014) finding that academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in in-label use of promoted drugs); Puneet Manchanda *et al., Responsiveness of Physician Prescription Beahavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am, J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997 to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls).

184. The Sackler brothers—Arthur, Mortimer, and Raymond—purchased a small patent-medicine company called the Purdue Frederick Company in 1952. It was Arthur Sackler who created the pharmaceutical advertising industry as we know it, laying the groundwork for the OxyContin promotion that would make the Sacklers billionaires.

185. Arthur Sackler was both a psychiatrist and a marketing executive. He pioneered both print advertising in medical journals and promotion through physician "education" in the form of seminars and continuing medical education courses. He also understood the persuasive power of recommendations from fellow physicians, and did not hesitate to manipulate information when necessary. For example, one promotional brochure produced by his firm for Pfizer showed business cards of physicians from various cities as if they were testimonials for the drug, but when a journalist tried to contact these doctors, he discovered that they did not exist.

186. It was Arthur Sackler who, in the 1960s, made Valium into the first $100-million drug, so popular it became known as "Mother's Little Helper." When Arthur's client, Roche, developed Valium, it already had a similar drug, Librium, another benzodiazepine, on the market for treatment of anxiety. So, Arthur invented a condition he called "psychic tension"—essentially stress—and pitched Valium[119] as the solution. The campaign, for which Arthur was compensated based on volume of pills sold, was a remarkable success.

187. Arthur Sackler created not only the advertising for his clients but also the vehicle to bring their advertisements to doctors—a biweekly newspaper called the *Medical Tribune*,

[119] Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* 204 (Rodale 2003) (hereinafter "Meier"); *see also, One Family Reaped Billions From Opioids*, WBUR On Point (Oct. 23, 2017), http://www.wbur.org/onpoint/2017/10/23/one-family-reaped-billions- from-opioids.

which was distributed for free to doctors nationwide. Arthur also conceived a company now called IMS Health Holdings Inc., which monitors the prescribing practices of every doctor in the U.S. and sells this valuable data to pharmaceutical companies the like Marketing Conspirators, who utilize it to target and tailor their sales pitches to individual physicians.

188. After the Sackler brothers acquired the Purdue Frederick Company in 1952, Purdue sold products ranging from earwax remover to antiseptic, and it became a profitable business. As an advertising executive, Arthur Sackler was not involved, on paper at least, in running Purdue, which would have been a conflict of interest. Raymond Sackler became Purdue's head executive, while Mortimer Sackler ran Purdue's UK affiliate.

189. In the 1980s, Purdue, through its UK affiliate, acquired a Scottish drug producer that had developed a sustained-release technology suitable for morphine. Purdue marketed this extended-release morphine as MS Contin, and it quickly became Purdue's bestseller. As the patent expiration for MS Contin loomed, Purdue searched for a drug to replace it. Around that time, Raymond's oldest son, Richard Sackler, who was also a trained physician, became more involved in the management of the company. Richard had grand ambitions for the company; according to a long-time Purdue sales representative, "Richard really wanted Purdue to be big—I mean *really* big."[120] Richard believed Purdue should develop another use for its "Contin" timed-release system.

190. In 1990, Purdue's vice president of clinical research, Robert Kaiko, sent a memo to Richard and other executives recommending that the company work on a pill containing oxycodone. At the time, oxycodone was perceived as less potent than morphine, largely because

[120] Christopher Glazek, *The Secretive Family Making Billions from the Opioid Crisis*, Esquire (Oct. 16, 2017), http://www.esquire.com/news-politics/a12775932/sackler-family-oxycontin/.

it was most commonly prescribed as Percocet, a relatively weak oxycodone-acetaminophen combination pill. MS Contin was not only approaching patent expiration but had always been limited by the stigma associated with morphine. Oxycodone did not have that problem, and what's more, it was sometimes mistakenly called "oxycodeine," which also contributed to the perception of relatively lower potency, because codeine is weaker than morphine. Purdue acknowledged using this to its advantage when it later pled guilty to criminal charges of "misbranding" in 2007, admitting that it was "well aware of the incorrect view held by many physicians that oxycodone was weaker than morphine" and "did not want to do anything 'to make physicians think that oxycodone was stronger or equal to morphine' or to 'take any steps . . . that would affect the unique position that OxyContin'" held among physicians.[121]

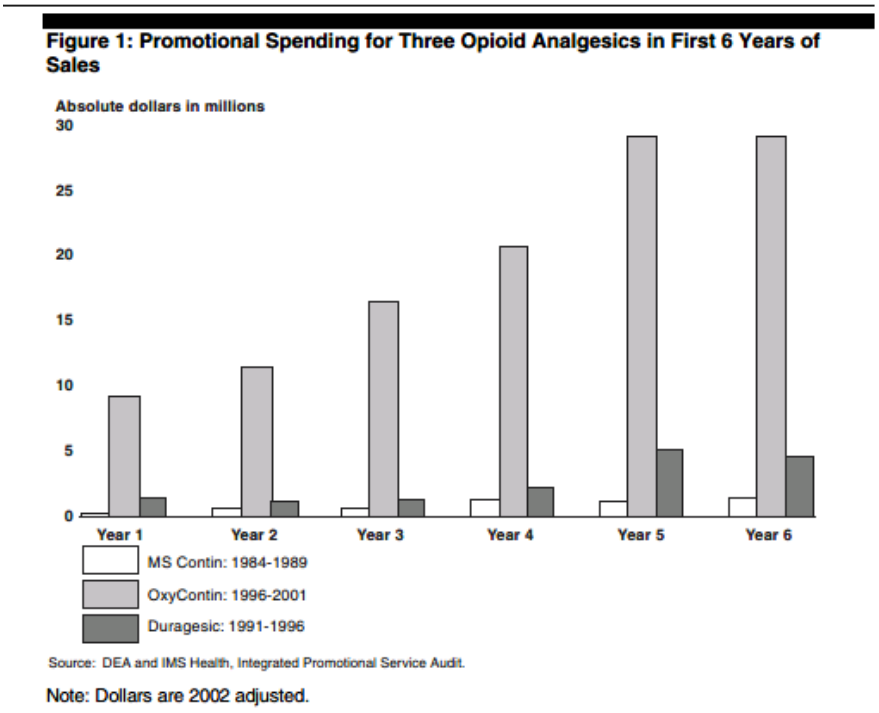
191. For Purdue and OxyContin to be "*really* big,"[122] Purdue needed to both distance its new product from the traditional view of narcotic addiction risk, and broaden the drug's uses beyond cancer pain and hospice care. A marketing memo sent to Purdue's top sales executives in March 1995 recommended that if Purdue could show that the risk of abuse was lower with OxyContin than with traditional immediate-release narcotics, sales would increase. As discussed below, Purdue did not find or generate any such evidence, but this did not stop Purdue from making that claim regardless.

192. Armed with this and other misrepresentations about the risks and benefits of its new drug, Purdue was able to open an enormous untapped market: patients with non-end-of-life, non-acute, everyday aches and pains. As Dr. David Haddox, a Senior Medical Director at Purdue, declared on the Early Show, a CBS morning talk program, "There are 50 million patients

[121] *Id*.
[122] *Id*.

in this country who have chronic pain that's not being managed appropriately every single day. OxyContin is one of the choices that doctors have available to them to treat that."[123]

In pursuit of these 50 million potential customers, Purdue poured resources into OxyContin's sales force and advertising, particularly to a far broader audience of primary care physicians who treated patients with chronic pain complaints. The graph below shows how promotional spending in the first six years following OxyContin's launch dwarfed Purdue's spending on MS Contin or Janssen's spending on Duragesic[124]



193. Prior to Purdue's launch of OxyContin, no drug company had ever promoted such a pure, high-strength Schedule II narcotic to so wide an audience of general practitioners.

[123] Meier, *supra* note 13, at 156.

[124] U.S. General Accounting Office, *OxyContin Abuse and Diversion and Efforts to Address the Problem*, U.S. General Accounting Office Report to Congressional Requesters, at 22 (Dec.2003), http://www.gao.gov/new/items/d04110.pdf.

194. In the two decades following OxyContin's launch, Purdue continued to devote substantial resources to its promotional efforts.

195. Purdue has generated estimated sales of more than $35 billion from opioids since 1996, raking in more than $3 billion in 2015 alone. Remarkably, its opioid sales continued to climb even after a period of media attention and government inquiries regarding OxyContin abuse in the early 2000s and a criminal investigation culminating in guilty pleas in 2007. Purdue proved itself skilled at evading full responsibility and continuing to sell through the controversy. The company's annual opioid sales of $3 billion in 2015 represent a four-fold increase from its 2006 sales of $800 million.

196. And since 2007, Purdue directed its highly trained and highly incentivized in-state opioid sales force to make more than half a million sales calls on Pennsylvania prescribers. In fact, excluding California, Purdue made more sales visits in Pennsylvania than any other state. Purdue trained its sales force to deliver a misleading and deceptive message to prescribers about the effectiveness and addictive nature of Purdue' s opioids more than 500,000 times.

197. One might imagine that Richard Sackler's ambitions have been realized. But in the best tradition of family patriarch Arthur Sackler, Purdue has its eyes on even greater profits. Under the name of Mundipharma, the Sacklers are looking to new markets for their opioids—employing the exact same playbook in South America, China, and India as they did in the United States.

198. In May 2017, a dozen members of Congress sent a letter to the World Health Organization, warning it of the deceptive practices Purdue is unleashing on the rest of the world through Mundipharma:

> We write to warn the international community of the deceptive and dangerous practices of Mundipharma

> International—an arm of Purdue Pharmaceuticals. The greed and recklessness of one company and its partners helped spark a public health crisis in the United States that will take generations to fully repair. We urge the World Health Organization (WHO) to do everything in its power to avoid allowing the same people to begin a worldwide opioid epidemic. Please learn from our experience and do not allow Mundipharma to carry on Purdue's deadly legacy on a global stage. . . .
>
> Internal documents revealed in court proceedings now tell us that since the early development of OxyContin, Purdue was aware of the high risk of addiction it carried. Combined with the misleading and aggressive marketing of the drug by its partner, Abbott Laboratories, Purdue began the opioid crisis that has devastated American communities since the end of the 1990s. Today, Mundipharma is using many of the same deceptive and reckless practices to sell OxyContin abroad. . . .
>
> In response to the growing scrutiny and diminished U.S. sales, the Sacklers have simply moved on. On December 18, the Los Angeles Times published an extremely troubling report detailing how in spite of the scores of lawsuits against Purdue for its role in the U.S. opioid crisis, and tens of thousands of overdose deaths, Mundipharma now aggressively markets OxyContin internationally. In fact, Mundipharma uses many of the same tactics that caused the opioid epidemic to flourish in the U.S., though now in countries with far fewer resources to devote to the fallout. [125]

199. Purdue's recent pivot to untapped markets—after extracting substantial profits from American communities and leaving local governments to address the devastating and still growing damage the company caused—only serves to underscore that Purdue's actions have been knowing, intentional, and motivated by profits throughout this entire story.

B. Other Marketing Conspirators Leapt at the Opioid Opportunity

200. Purdue created a market for the use of opioids for a range of common aches and pains by misrepresenting the risks and benefits of its opioids, but it was not alone. The other

[125] Letter from Members of Congress to Dr. Margaret Chan, Director-General, World Health Organization (May 3, 2017), http://katherineclark.house.gov/_cache/files/a577bd3c-29ec-4bb9- bdba-1ca71c784113/mundipharma-letter-signatures.pdf.

Marketing Conspirators—already manufacturers of prescription opioids—positioned themselves to take advantage of the opportunity Purdue created, developing both branded and generic opioids to compete with OxyContin, while, together with Purdue and with each other, misrepresenting the safety and efficacy of their products. These misrepresentations are described in greater detail below.

201. Endo, which already sold Percocet and Percodan, was the first to submit an application for a generic extended-release oxycodone to compete with OxyContin. At the same time, Endo sought FDA approval for another potent opioid, immediate-release and extended-release oxymorphone, branded as Opana and Opana ER. Oxymorphone, like OxyContin's active ingredient oxycodone, is not a new drug; it was first synthesized in Germany in 1914 and sold in the U.S. by Endo beginning in 1959 under the trade name Numorphan. But Numorphan tablets proved highly susceptible to abuse. Called "blues" after the light blue color of the 10 mg pills, Numorphan provoked, according to some users, a more euphoric high than heroin. As the National Institute on Drug Abuse observed in its 1974 report, "Drugs and Addict Lifestyle," Numorphan was extremely popular among addicts for its quick and sustained effect.[126] Endo withdrew oral Numorphan from the market in 1979.

202. Two decades later, however, as communities around the U.S. were first sounding the alarm about prescription opioids and Purdue executives were being called to testify before Congress about the risks of OxyContin, Endo essentially reached back into its inventory, dusted off a product it had previously shelved after widespread abuse, and pushed it into the marketplace with a new trade name, Opana.

[126] John Fauber & Kristina Fiore, *Abandoned Painkiller Makes a Comeback*, MedPage Today (May 10, 2015), https://www.medpagetoday.com/psychiatry/addictions/51448.

203. The clinical trials submitted with Endo's first application for approval of Opana were insufficient to demonstrate efficacy, and some subjects in the trials overdosed and had to be revived with naloxone. Endo then submitted new "enriched enrollment" clinical trials, in which trial subjects who do not respond to the drug are excluded from the trial, and obtained approval. Endo began marketing Opana and Opana ER in 2006.

204. Like Numorphan, Opana ER was highly susceptible to abuse. On June 8, 2017, the FDA sought removal of Opana ER. In its press release, the FDA indicated that "[t]his is the first time the agency has taken steps to remove a currently marketed opioid pain medication from sale due to the public health consequences of abuse."[127]

205. On July 6, 2017, Endo agreed to withdraw Opana ER from the market. Janssen, which already marketed the Duragesic (fentanyl) patch for severe pain, also joined Purdue in pursuit of the broader chronic pain market. It sought to expand the use of Duragesic through, for example, advertisements proclaiming, "It's not just for end stage cancer anymore!"[128] This claim earned Janssen a warning letter from the FDA, for representing that Duragesic was "more useful in a broader range of conditions or patients than has been demonstrated by substantial evidence."[129]

206. Janssen also developed a new opioid compound called tapentadol in 2009, marketed as Nucynta for the treatment of moderate to severe pain. Janssen launched the extended- release version, Nucynta ER, for treatment of chronic pain in 2011.

207. By adding additional opioids or expanding the use of their existing opioid

[127] Press Release, U.S. Food & Drug Admin., *FDA Requests Removal of Opana ER for Risks Related to Abuse* (June 8, 2017), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm.
[128] Letter from U.S. Food & Drug Admin. to Janssen (Mar. 30, 2000) at 2.
[129] *Id.*

products, the other Marketing Conspirators took advantage of the market created by Purdue's aggressive promotion of OxyContin and reaped enormous profits.

208. For example, Opana ER alone generated more than $1 billion in revenue for Endo in 2010 and again in 2013. Janssen also passed the $1 billion mark in sales of Duragesic in 2009.

C. The Marketing Conspirators Targeted Vulnerable Populations.

209. With respect to the patients and consumers who would potentially seek and purchase their products, the Marketing Conspirators specifically targeted their marketing at two vulnerable populations—the elderly and veterans.

210. Elderly patients taking opioids have been found to be exposed to elevated fracture risks, a greater risk for hospitalizations, and increased vulnerability to adverse drug effects and interactions, such as respiratory depression which occurs more frequently in elderly patients.

211. The Marketing Conspirators promoted the notion—without adequate scientific foundation—that the elderly are particularly unlikely to become addicted to opioids. The AGS 2009 Guidelines, for example, which Purdue, Endo, and Janssen publicized, described the risk of addiction as "*exceedingly low* in older patients with no current or past history of substance abuse." (emphasis added). As another example, an Endo-sponsored Continuing Medical Education ("CME") put on by NIPC, *Persistent Pain in the Older Adult*, taught that prescribing opioids to older patients carried "possibly less potential for abuse than in younger patients." Contrary to these assertions, however, a 2010 study examining overdoses among long-term opioid users found that patients 65 or older were among those with the largest number of serious overdoses.

212. Similarly, Endo targeted marketing of Opana ER towards patients over 55 years old. Such documents show Endo treated Medicare Part D patients as among the "most valuable customer segments." However, in 2013, one pharmaceutical benefits management company recommended against the use of Opana ER for elderly patients and unequivocally concluded: "[f]or patients 65 and older these medications are not safe, so consult your doctor."

213. According to a study published in the 2013 *Journal of American Medicine*, veterans returning from Iraq and Afghanistan who were prescribed opioids have a higher incidence of adverse clinical outcomes, such as overdoses and self-inflicted and accidental injuries. A 2008 survey showed that prescription drug misuse among military personnel doubled from 2002 to 2005, and then nearly tripled again over the next three years. Veterans are twice as likely as non-veterans to die from an opioid overdose.

214. Yet the Marketing Conspirators deliberately targeted veterans with deceptive marketing. For example, a 2009 publication sponsored by Purdue, Endo, and Janssen, and distributed by APF with grants from Janssen and Endo, was written as a personal narrative of one veteran but was in fact another vehicle for opioid promotion. Called *Exit Wounds*, the publication describes opioids as "underused" and the "gold standard of pain medications" while failing to disclose significant risks of opioid use, including the risks of fatal interactions with benzodiazepines. According to a VA Office of Inspector General Report, 92.6% of veterans who were prescribed opioid drugs were also prescribed benzodiazepines, despite the increased danger of respiratory depression from the two drugs together.

215. Opioid prescriptions have dramatically increased for veterans and the elderly. Since 2007, prescriptions for the elderly have grown at twice the rate of prescriptions for adults between the ages of 40 and 59. And in 2009, military doctors wrote 3.8 million prescriptions for

narcotic pain pills—four times as many as they did in 2001.

D. The Marketing Conspirators' Marketing Strategy Worked

216. As detailed elsewhere in this Complaint, the Marketing Conspirators' misrepresentations fall into the following nine categories:

a. The risk of addiction from chronic opioid therapy is low;
b. To the extent there is a risk of addiction, it can be easily identified and managed;
c. Signs of addictive behavior are "pseudoaddiction," requiring more opioids;
d. Opioid withdrawal can be avoided by tapering;
e. Opioid doses can be increased without limit or greater risks;
f. Long-term opioid use improves functioning;
g. Alternative forms of pain relief pose greater risks than opioids;
h. OxyContin provides twelve hours of pain relief; and
i. New formulations of certain opioids successfully deter abuse;;

217. Each of these propositions was false. The Marketing Conspirators knew this, but they nonetheless set out to convince physicians, patients, and the public at large of the truth of each of these propositions in order to expand the market for their opioids.

218. The Marketing Conspirators' false and misleading marketing was effective in convincing prescribers, pharmacists, patients, third party payors, pharmacy benefit managers, health plan administrators, and others for selecting and approving prescription opioids covered by health insurance plans that opioids could be safety used on a long-term basis to treat chronic pain; that opioids were an effective treatment for chronic pain; and that benefits of using opioids to treat chronic pain far outweighed the risks.

219. The Marketing Conspirators' marketing campaigns specifically targeted prescribers, pharmacists, and patients, as well as individuals and groups responsible for selecting opioid drugs covered by health coverage plans and included on pharmacy formularies (*i.e.*,

insurers, pharmacy benefit managers, and others).

220. The Marketing Conspirators, however, knew that these marketing and product promotion claims were false, misleading, and likely to misinform or confuse the targets of the marketing and product promotion described above. The Marketing Conspirators knew that, as set forth above, controlled studies of the safety and efficacy of prescription opioids were limited to short-term use in monitored settings (*e.g.*, hospitals) where the risks of addiction and other adverse outcomes were minimized, and long-term studies demonstrating the safety and efficacy of prescription opioids for long-term use did not exist.

221. The Marketing Conspirators also knew or disregarded that the effectiveness of prescription opioids wanes with prolonged use, requiring increases in dosage to achieve ongoing pain relief, which, markedly increases the risk of significant side effects, addiction, and overdose when used for long-term treatment.

222. Despite these facts – well known to the Marketing Conspirators for many years – the Marketing Conspirators sought to create a false perception of the safety and efficacy of opioids for long-term daily use, including the treatment of such common ailments as headache, lower back pain, and arthritis.

223. The Marketing Conspirators engaged in this deceptive conduct because they recognized that chronic pain patients could provide a much larger, and far more lucrative, market for prescription opioids than patients with cancer pain at the end of life. To take advantage of this massive market, the Marketing Conspirators engaged in marketing activities to promote prescription opioids for the management of chronic pain, thereby elevating corporate profits above the interest of patients.

224. The Marketing Conspirators created a favorable perception of prescription opioids

through coordinated, sophisticated, and highly deceptive marketing that began in the mid-1990s and continued for years thereafter.

225. In 1996, opioid sales and use began accelerating rapidly. As discussed above, this acceleration was triggered initially by the introduction in 1995 of Purdue's OxyContin, an extended release formulation of oxycodone, and Purdue's aggressive marketing of OxyContin. Other Marketing Conspirators followed suit and began to aggressively market their own prescription opioids in a similar manner. The rapid acceleration of sales and use of prescription opioids continued for two decades, as described above.

226. During this time, the Marketing Conspirators individually and collectively poured vast financial resources into marketing their own opioids products to distort medical and public perceptions of prescriptions opioids and create the false impressions of a new "consensus" supporting the long-term daily use of opioids. Marketing Conspirators' misleading tactics were wide-reaching and varied.

227. Specifically, as discussed more fully below, the Marketing Conspirators: (i) misrepresented that prescriptions opioids improved patients' function; (ii) concealed the link between long-term use of prescriptions opioids and addiction; (iii) misrepresented that addiction risk could be effectively managed; (iv) masked the signs of addiction by promoting the misleading concept of "pseudoaddiction"; (v) falsely claimed that withdrawal symptoms could be easily addressed; (vi) misrepresented that increasing patient doses posed no significant additional health risks; and (vii) overstated the risks and understated the efficacy of non-opioid based alternative pain treatments.

228. The Marketing Conspirators made these misleading statements concerning both their own branded products and prescription opioids generally. The Marketing Conspirators

made these misrepresentations directly in their own marketing materials, as well as indirectly through the use of third party vehicles including: (i) so-called "key opinion leaders" ("KOLs"), *i.e.*, physicians who influence their peers' medical practices and prescribing behavior, who wrote favorable journal articles and delivered supportive educational courses; (ii) "unbranded" education materials for patients, physicians and others disseminated through groups purporting to be independent patient-advocacy and professional organizations ("Front Groups"), which exercised influence through Marketing Conspirator-controlled KOLs who served in leadership roles in these organizations and which were directly or indirectly controlled by the Marketing Conspirators; (iii) a body of biased and unsupported scientific literature which the Marketing Conspirators directly or indirectly created, funded, or exploited: and (iv) so-called "treatment guidelines" which the Marketing Conspirators formulated or caused to be formulated; and (v) CMEs prepared and/or funded in whole or in part by the Marketing Conspirators. These third parties and third party vehicles are collectively referred to herein as the Marketing Conspirators' "Third Party Allies."

229. The Marketing Conspirators' direct and indirect approach, including use of purportedly independent third parties to lend credibility to the messaging ("third party validators"), was very effective. The Marketing Conspirators' efforts successfully altered the prescribing practices of the medical community, thereby dramatically increasing opioid prescription volumes and use. These efforts also successfully influenced third party payors, pharmacy benefit managers (PBMs") and others responsible for maintaining and administering drug formularies on behalf of private and public health insurance plans.

230. Over-prescriptions of opioids resulting from the deceptive over-promotion by the Marketing Conspirators led to an artificial inflation of demand for prescriptions opioids. This

created a population of users physically dependent on opioids, thereby leading to dramatically increased sales of prescriptions opioids, all to the improper and direct financial benefit of the Marketing Conspirators.

231. The Marketing Conspirators' broad marketing efforts have, indeed been enormously profitable. In 2015, prescription opioids generated $9.6 billion in revenue for opioids manufacturers.[130] By 2016, Defendant Purdue alone had generated $35 billion in revenue from the sale of OxyContin since the product's inception.[131]

232. The vast demand for opioids today is sustained largely by the Marketing Conspirators' prior success in marketing and establishing prescriptions opioids as a treatment for chronic pain. The current demand for prescription opioids is comprised of individuals suffering from physiological dependence who require continued opioid prescriptions (and their agent-doctors who refill opioid prescriptions in the continued belief that opioids are safe in light of the Marketing Conspirators' prior product promotion) and new patients who, along with their physicians, wrongly believe that opioids are a viable and safe chronic pain treatment.

233. The Marketing Conspirators directed their misleading marketing efforts not only to physicians, pharmacists and patients, but also to third-party payors, PBMs and other health plan administrators including those responsible for approving Marketing Conspirators' drugs for inclusion on drug formularies.

234. Physicians, along with formulary committees of third-party payors and PBMs, rely upon a variety of sources including independent studies for information relating to the safety and efficacy of prescription drug which they prescribe or approve for use. However, often

[130] D. Crow, *Drugmakers Hooked on $10bn Opioid Habit*, Financial Times (Aug. 10, 2016), *available at* https://www.ft.com/content/f6c989a8-5dac-11e6-bb77-a121aa8abd95.
[131] Patrick Radden Keefe, *The Family That Built an Empire of Pain*, The New Yorker (Oct. 30, 2017), *available at* http://www.newyorker.com/magazine/2017/30/the-family-that-build-an-empire-of-pain.

unbeknownst to the public and other persons and entities, many of these sources are directly controlled or heavily influenced by pharmaceutical manufacturers such as the Marketing Conspirators, Also, many of these sources of information are susceptible to exploitation by pharmaceutical manufacturers such as the Marketing Conspirators.

235. The Marketing Conspirators' culpability is not absolved or mitigated by the involvement of doctors in the prescription process or clinical evaluators at the third-party payors, PBMs or other health plan administrators. The Marketing Conspirators' deceptive marketing efforts were both widespread and highly persuasive. Their deceptive messages tainted many sources which doctors and health plan administrators relied on for information, and prevented them from making fully informed treatment decisions. The Marketing Conspirators targeted not only pain specialists, but also primary care physicians, nurse practitioners, physicians' assistants, and other non-pain specialists who were even less likely to be able to assess Marketing Conspirators' misleading statements, as well as clinical evaluators at or used by health plan administrators.

VI. The Marketing Conspirators Used "Branded" and "Unbranded" Opioid Marketing to Deceive Physicians, Patients, Pharmacy Benefit Managers and Vulnerable Populations

236. Drug companies' promotional activities can be characterized as "branded" or "unbranded." Branded marketing refers to marketing of a specific drug manufactured by a specific company. Unbranded marketing refers not to the marketing of a specific drug or brand, but rather a class of drugs or a particular disease, condition, or treatment.

A. The Marketing Conspirators' Deceptive Branded Marketing of Opioids

237. Branded marketing generally must be consistent with a product's label, be supported by substantial scientific evidence, and not include false or misleading statements or

material omissions about the safety and/or efficacy of the drug.

238. Drug companies, which are regarded as best suited to be knowledgeable about the properties and effects of their drugs, are responsible for providing prescribers, third-party payors, PBMs and other health plan administrators with information they need to accurately assess the risks and benefits of drugs for their patients and insureds.

239. Product marketing and promotion that fails to state accurately the safety, efficacy and risks of a prescription drug, or which fails to present the most important risks of the drug as prominently as its benefits, is deceptive on its face or it lacks fair balance and is, therefore, deceptive.

240. It is also improper for Marketing Conspirators to distribute materials or make promotional statements that exclude contrary evidence or information about the drug's safety or efficiency, or present conclusions that are not supported by the results of clinical or other studies.

241. Further, it is improper for Marketing Conspirators to make comparisons between their drugs and other drugs treating the same condition that represent or suggest that their drugs are safer or more effective, when they have not been demonstrated to be safer or more effective based on substantial evidence or substantial clinical experience.

242. The Marketing Conspirators made misleading statements in their branded marketing (as set forth herein). In addition to direct statements concerning safety and efficacy in connection with their branded marketing, the Marketing Conspirators also brought to the attention of their target audience – physicians, patients, third-party payors, PBMs and others – the unbranded marketing set forth below.

B. The Marketing Conspirators' Deceptive Unbranded Marketing of Opioids

243. The Marketing Conspirators often avoided using branded product promotion to

spread their improper messages regarding the efficacy and safety of company-specific opioids.

244. Instead, the Marketing Conspirators disseminated much of their false, misleading, unbalanced, and unsupported statements through unbranded marketing material – materials that promoted prescriptions opioid use but did not name a specific opioid while doing so. Through these unbranded materials and statements, the Marketing Conspirators presented information and guidelines concerning prescription opioids generally that were false and misleading.

245. Further, by acting through third parties, the Marketing Conspirators were able to give the false appearance that their messages reflected the views of independent unbiased sources.

246. The Marketing Conspirators falsely cited these sources as independent corroboration of their own statements.

247. Presenting these materials as third-party documents gave them not only greater credibility than other marketing propaganda, but also broader diffusion among practitioners in the medical profession. Many doctors who would generally resist displaying in their office materials from drug companies were comfortable displaying materials from purportedly independent entities.

248. The Marketing Conspirators disseminated many of their false, misleading, unbalanced and unsupported promotional messages through third party vehicles because the messages appeared to be independent. Through unbranded materials, the Marketing Conspirators presented information and guidance concerning opioids that were false, misleading, unsubstantiated, unbalanced, and incomplete.

249. Even where unbranded messages were disseminated through third-party vehicles, the Marketing Conspirators adopted those messages as their own when they cited to, edited,

approved, and distributed such materials in their direct marketing activities knowing they were false, misleading, unsubstantiated, unbalanced, and incomplete.

250. The Marketing Conspirators' sales representatives regularly distributed deceptive third-party marketing materials to the Marketing Conspirators' target audience, including physicians, patients, pharmacy benefit managers, formularies, insurers, third-party payors, health plan administrators and other participants in the prescribing or third-party approval chain.

251. The Marketing Conspirators took an active role in guiding, reviewing, and approving many of the misleading statements issued by third parties, ensuring that Marketing Conspirators were consistently in control of the content. By funding, directing, editing, and distributing these materials, the Marketing Conspirators exercised control over their deceptive messages and acted in concert with these third parties to promote the use of prescription opioids for the treatment of chronic pain.

252. The unbranded marketing materials that Marketing Conspirators assisted in creating and disseminating failed to properly disclose the risks of opioid addiction, abuse, misuse, and overdose, or wrongfully denied or minimized those risks as alleged more fully herein. Those materials also misrepresented or concealed information concerning the efficacy of prescription opioids as a treatment for chronic pain.

1. The Marketing Conspirators' Use of Key Opinion Leaders to Further their Deceptive Marketing

253. The Marketing Conspirators cultivated a select group of doctors who were chosen and sponsored by the Marketing Conspirators solely because they favored the aggressive treatment of chronic pain with prescription opioids. Pro-opioid doctors have been at the hub of the Marketing Conspirators' promotional efforts, presenting the appearance of unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain.

Pharmaceutical companies have hired KOLs to influence prescribing practices of their peers. Misleading statements and materials created by KOLs were directly or indirectly disseminated to patients, physicians, and others including third-party payors, PBMs and other health plan administrators.

254. These pro-opioid doctors have written, consulted on, edited, and lent their names to numerous books and articles, and given speeches and CMEs supportive of opioid therapy for treatment of chronic pain.

255. These same doctors served on committees that developed so-called "treatment guidelines" that strongly encouraged the use of prescription opioids to treat chronic pain, and on boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. The Marketing Conspirators were able to exert influence and control over each of these modalities through the KOLs.

256. In return for their pro-opioid advocacy, the Marketing Conspirators' KOLs received money, prestige, recognition, research funding, and avenues to publish. It is now clear that both written and oral statements by the Marketing Conspirators' KOLs either were false and misleading or lacked reasonable medical or scientific bases in fact.

257. The Marketing Conspirators cited and promoted their KOLs – and studies or articles by their KOLs – to broaden the chronic opioid therapy market. By contrast, the Marketing Conspirators did not support, acknowledge, or disseminate the publications or studies of doctors who were critical of the use of chronic opioid therapy.

258. The Marketing Conspirators carefully vetted their KOLs to ensure that they were likely to remain on-message and supportive of the Marketing Conspirators' agenda. The Marketing Conspirators also kept close tabs on the content of the materials published by these

KOLs.

259. In their promotion of the use of opioids to treat chronic pain, the Marketing Conspirators' KOLs knew that their statements were false and misleading, or recklessly disregarded the truth in doing so, yet they continued to publish and voice their misleading messages to benefit themselves and the Marketing Conspirators. The cooperation of some of the most prominent KOLs with the Marketing Conspirators is described below. On information and belief, there were a number of other similarly compromised KOLs.

a. Dr. Russel Portenoy's Role in Marketing Conspirators' Deceptive Marketing of Opioids

260. Dr. Portenoy, former chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom the Marketing Conspirators identified and promoted to further their marketing campaigns.

261. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, and Purdue (among other Defendants), and was a paid consultant to Cephalon and Purdue.

262. Dr. Portenoy was instrumental in opening the door for the regular use of prescriptions opioids to treat chronic pain. He served on the American Pain Society ("APS") and American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of prescriptions opioids to treat chronic pain first in 1997 and again in 2009. He was also a member of the board of the American Pain Foundation "(APF), an advocacy organization almost entirely funded by the Marketing Conspirators.

263. Dr. Portenoy also made frequent media appearances promoting prescription opioids and spreading misinformation on Marketing Conspirators' behalf.

264. For example, he appeared on *Good Morning America* in 2010 to discuss the use

of opioids to treat chronic pain. On this widely watched program, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that the person is not going to become addicted."[132]

265. Dr. Portenoy subsequently admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true."[133] Among other things, these lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors that promoted them overstated opioids' benefits and glossed over their risks.[134]

266. Dr. Portenoy also conceded to *The Wall Street Journal* that "[d]ata about the effectiveness of opioids does not exist."[135] He candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, … I guess I did."[136]

267. According to news reporting, Dr. Portenoy "recanted publicity in 2011, conceding that research he relied on to push his and Purdue's pro-opioid campaign didn't prove anything about the treatment of chronic pain."[137]

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[132] *Good Morning America* television broadcast, ABC News (Aug. 30, 2010).
[133]Thomas Catan et al., *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal (Dec. 17, 2012), available at https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.
[134] *Id.*
[135] *Id.*
[136] *Id.*
[137] Esme Deprez. *The Lawyer Who Beat Big Tobacco Takes on the Opioid Industry*, Bloomberg Businessweek (Oct. 5, 2017), *available at* http://www.bloomberg.com/news/features/2017-10-05/the-lawyer-who-beat-big-tobacco-takes-on-the-opioid-industry.

b. Dr. Lynn Webster's Role in Marketing Conspirators' Deceptive Marketing of Opioids

268. Another KOL, Dr. Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, a pain clinic in Salt Lake City, Utah, and he served as President in 2013. Dr. Webster was also a former board member of AAPM, a front group that ardently supports chronic opioid therapy. He was a Senior Editor of *Pain Medicine*, the same journal that published Defendant Endo's special advertising supplements touting Opana Er.

269. Dr. Webster authored numerous CMEs sponsored by Marketing Conspirators Cephalon, Endo, and Purdue and received significant funding from others, including Insys and Mallinckrodt. Dr. Webster received nearly $2 million from Cephalon alone.

270. Dr. Webster created and promoted the Opioid Risk Tool,[138] a ten question, one-minute screening tool relying on patient self-reporting that purportedly allows doctors to manage the risk that patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term; for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appeared on, or were linked to, websites run by some of the Defendants, including Endo, Janssen, and Purdue.

271. In 2011, Dr. Webster presented, via webinar, a program sponsored by Defendant Purdue titled *Managing Patient's Opioid Use Balancing the Need and the Risk.* Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths."

272. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction,"

[138] https://www.drugabuse.gov/sites/default/files/OpioidRiskTool.pdf.

the notion that addictive behaviors should be seen not as warnings, but as indications of *undertreated* pain. In Dr. Webster's description, the only way to differentiate between addiction and undertreated pain was to increase a patient's dose of opioids. As he and his co-author wrote in a book titled *Avoiding Opioid Abuse While Managing Pain* (2007), when faced with signs of aberrant behavior, increasing the dose "in most cases … should be the clinician's first response."[139] Defendant Endo distributed this book to many doctors.

273. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[140]

274. As part of an investigation into his overprescribing of opioids, the DEA raided Dr. Webster's clinic in 2010.[141]

275. More than 20 of Dr. Webster's former patients at the Lifetree clinic have died of opioid overdoses. [142]

c. Dr. Perry Fine's Role in Marketing Conspirators' Deceptive Marketing of Opioids

276. Dr. Perry Fine's ties to the Marketing Conspirators are well documented. He has authored articles and testified in court cases and before state and federal committees, and he, too, has argued against legislation restricting high-dose opioid prescription for non-cancer patients.

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[139] *See* book excerpt *available at* https://books.google.com/books?id=1C_DRcKq_KwC&pg=PT99&lpg=PT99&dq=%22Avoiding+Opioid+Abuse+While+Managing+Pain%22+%22clinician%E2%80%99s+first+response%22&source=bl&ots=DetEK1gFua&sig=1QiiklPhKQldfmLayEF-YIDTRfo&hl=cn&sa=X&ved%E2%80%940ahUKEwiZ7aep78DWAhV10FQKHUF3CjUQ6AEIJjAA#v=onepage&q=%22Avoiding%20Opioid%20Abuse%20While%20Managing%20Pain%22%20%22clinician%E2%80%99s%20first%20response%22&f=false.

[140] John Fauber et al., *Networking Fuels Painkiller Boom*, Milwaukee Wisconsin Journal Sentinel (Feb. 19, 2012), *available at* http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2m=139609053.html/.

[141] Stephanie Smith, *Prominent Pain Doctor Investigated by DEA After Patient Deaths*, CNN (Dec. 20, 2013), *available at* http://www.cnn.com/2013/12/20/health/pain-pillar/index.html.

[142] Jess Hyde, *The untold story of how Utah doctors and Big Pharma helped drive the national opioid epidemic*, Deseret News (Oct. 27, 2017), *available at* https://www.deseretnews.com/article/900002328/the-untold-story-of-how-utah-doctors-and-big-pharma-helped-drive-the-national-opioid-epidemic.html.

He has served on Purdue's advisory board, provided medical legal consulting for Janssen, and participated in CME activities for Endo, along with serving in these capacities for several other drug companies. He co-chaired the APS/AAPM Opioid Guideline Panel, served as treasurer of the AAPM from 2007 to 2010 and as president of that group from 2011 to 2013, and was on the board of directors of APF.

277. Dr. Fine testified at trial that the 1,500 pills a month prescribed to celebrity Anna Nicole Smith for pain did not make her an addict before her death.

278. He has also acknowledged having failed to disclose numerous conflicts of interest. For example, Dr. Fine failed to fully disclose payments (as required) received by his employer, the University of Utah—telling the university that he had received under $5,000 in 2010 from J&J for providing "educational" services, but J&J's website states that the company paid him $32,017 for consulting, promotional talks, meals and travel that year.

279. Dr. Fine and Dr. Portenoy co-wrote *A Clinical Guide to Opioid Analgesia*, in which they downplayed the risks of opioid treatment, such as respiratory depression and addiction:

> At clinically appropriate doses, . . . respiratory rate typically does not decline. Tolerance to the respiratory effects usually develops quickly, and doses can be steadily increased without risk.
>
> Overall, the literature provides evidence that the outcomes of drug abuse and addiction are rare among patients who receive opioids for a short period (ie, for acute pain) and among those with no history of abuse who receive long-term therapy for medical indications.[143]

[143] Perry G. Fine, MD & Russell K. Portenoy, MD, *A Clinical Guide to Opioid Analgesia*, McGraw- Hill Companies, 2004, at 20,34, http://www.thblack.com/links/RSD/OpioidHandbook.pdf.

280. In November 2010, Dr. Fine and others published an article presenting the results of another Cephalon-sponsored study titled "Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study."[144] In that article, Dr. Fine explained that the 18-month "open-label" study "assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP in a large cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for noncancer pain." The article acknowledged that: (a) "[t]here has been a steady increase in the use of opioids for the management of chronic noncancer pain over the past two decades"; (b) the "widespread acceptance" had led to the publishing of practice guidelines "to provide evidence-and consensus-based recommendations for the optimal use of opioids in the management of chronic pain"; and (c) those guidelines lacked "data assessing the long-term benefits and harms of opioid therapy for chronic pain."[145]

281. The article concluded: "[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable, manageable, and tolerable." They also conclude that the number of abuse-related events was "small." [146]

282. Multiple videos feature Dr. Fine delivering educational talks about the drugs. In one video from 2011 titled "Optimizing Opioid Therapy," he sets forth a "Guideline for Chronic Opioid Therapy" discussing "opioid rotation" (switching from one opioid to another) not only for cancer patients, but for non-cancer patients, and suggests it may take four or five switches

[144] Perry G. Fine, et al., Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study, 40(5) J. Pain & Symptom Mgmt. 747-60 (Nov. 2010).
[145] *Id*. at 748.
[146] *Id*. at 759.

over a person's "lifetime" to manage pain.[147] He states the "goal is to improve effectiveness which is different from efficacy and safety." Rather, for chronic pain patients, effectiveness "is a balance of therapeutic good and adverse events *over the course of years*." The entire program assumes that opioids are appropriate treatment over a "protracted period of time" and even over a patient's entire "lifetime." He even suggests that opioids can be used to treat *sleep apnea*. He further states that the associated risks of addiction and abuse can be managed by doctors and evaluated with "tools," but leaves that for "a whole other lecture." [148]

d. Dr. Scott Fishman's Role in Marketing Conspirators' Deceptive Marketing of Opioids

283. Dr. Scott Fishman is a physician whose ties to the opioid drug industry are legion. He has served as an APF board member and as president of the AAPM, and has participated yearly in numerous CME activities for which he received "market rate honoraria." As discussed below, he has authored publications, including the seminal guides on opioid prescribing, which were funded by the Marketing Conspirators. He has also worked to oppose legislation requiring doctors and others to consult pain specialists before prescribing high doses of opioids to non-cancer patients. He has himself acknowledged his failure to disclose all potential conflicts of interest in a letter in the *Journal of the American Medical Association* titled "Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion."[149]

284. In 2007, Dr. Fishman authored a physician's guide on the use of opioids to treat

[147] Perry A. Fine, *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), https://www.youtube.com/watch?v=_G3II9yqgXI.
[148] *Id*.
[149] Scott M. Fishman, Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion, 306 (13) JAMA 1445 (Sept. 20, 2011), https://jamanetwork.com/journals/jama/article-abstract/1104464?redirect=true; Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011, 9:14 AM), https://www.propublica.org/article/two-leaders-in-pain-treatment- have-long-ties-to-drug-industry.

chronic pain titled *Responsible Opioid Prescribing*, which promoted the notion that long-term opioid treatment was a viable and safe option for treating chronic pain.

285. In 2012, Dr. Fishman updated the guide and continued emphasizing the "catastrophic" "under-treatment" of pain and the "crisis" such under-treatment created:

> Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce diversion and misuse of prescription opioids, it's critical to remember that the problem of unrelieved pain remains as urgent as ever.[150]

286. The updated guide still assures that "[o]pioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and noncancer origins." [151]

287. In another guide by Dr. Fishman, he continues to downplay the risk of addiction: "I believe clinicians must be very careful with the label 'addict.' I draw a distinction between a 'chemical coper' and an addict."[152] The guide also continues to present symptoms of addiction as symptoms of "pseudoaddiction."

2. The Marketing Conspirators' Misuse of Patient and Physician Education Materials and Front Groups to Further Their Marketing of Opioids

288. Pharmaceutical industry marketing experts view patient-focused advertising, including direct-to-consumer marketing, as particularly valuable in "increas[ing] market share … by bringing awareness to a particular disease that the drug treats."[153]

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[150] Scott M. Fishman, Responsible Opioid Prescribing: A Guide for Michigan Clinicians, 10-11 (Waterford Life Sciences, 2d ed. 2012).
[151] *Id*..
[152] Scott M. Fishman, *Listening to Pain: A Physician's Guide to Improving Pain Management Through Better Communication* 45 (Oxford University Press 2012).
[153] Kanika Johar, *An Insider's Perspective: Defense of the Pharmaceutical Industry's Marketing Practices*, 76

289. Physicians are more likely to prescribe a drug if a patient specifically requests it, and physicians' willingness to acquiesce to such patient requests holds true for opioids.[154]

290. Recognizing this phenomenon, the Marketing Conspirators put their relationships with Front Groups to work to engage in largely unbranded patient education about opioid treatment for chronic pain.

291. The Marketing Conspirators entered into arrangements with numerous Front Groups to promote opioids. These organizations depended upon the Marketing Conspirators for significant funding and, in some cases, for their survival.

292. These "Front Groups" put out patient education materials, treatment guidelines and CMEs that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks.[155] Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages—often at the expense of their own constituencies.

293. Front Groups were involved not only in generating materials and programs for doctors and patients that supported chronic opioid therapy, but also in assisting Marketing Conspirators' marketing in other ways – for example, responding to negative articles and advocating against regulatory changes that would constrain opioid prescribing.

294. These Front Groups developed and disseminated pro-opioid treatment guidelines; conducted outreach to groups targeted by the Marketing Conspirators, such as veterans and the elderly; and developed and sponsored CMEs that focused exclusively on use of opioids to treat

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Albany L. Rev. 299, 308 (2013).

[154] In one study, for example, nearly 20% of sciatica patients requesting oxycodone received a prescription for it, compared with 1% of those making no specific request. J.B. McKinlay *et al.*, *Effects of Patient Medication Requests on Physician Prescribing Behavior*, 52(2) Med. Care 294 (2014).

[155] U.S. S. Homeland Sec. & Governmental Aff. Comm., Ranking Members' Office, *Fueling an Epidemic*, Feb. 12, 2018, https://www.hsdl.org/?abstract&did=808171 at 3 (hereinafter, "*Fueling an Epidemic*").

chronic pain.

295. The Marketing Conspirators funded these Front Groups in order to ensure supporting messages from seemingly neutral and credible third parties, and their funding did, in fact, ensure such supporting messages.

296. These Front Groups intended to, and did, disseminate these messages to a national audience, including, upon information and belief, within Allentown

297. Set forth immediately below are examples of the Front Groups used by the Marketing Conspirators.

a. The APF's Role in Marketing Conspirators' Deceptive Marketing of Opioids

298. The most prominent of the Marketing Conspirators' Front Groups was the American Pain Foundation ("APF"), which received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012.

299. APF issued purported "education guides" for patients, the news media, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addition. APF also engaged in a significant multimedia campaign through radio, television and the internet to purportedly "educate" patients about their "right" to pain treatment with opioids.

300. All of APF's programs and materials were intended to, and did, reach a national audience, including, upon information and belief, within Allentown.

301. By 2011, APF was entirely dependent on incoming grants from Marketing Conspirators Purdue, Cephalon, Endo, and others for funding, which also thereby enabled APF to avoid using its line of credit. APF board member, KOL Dr. Portenoy, explained that the lack of funding diversity was one of the biggest problems at APF.

302. APF held itself out as an independent patient advocacy organization, yet engaged in grassroots lobbying efforts against various legislative initiatives that might have limited opioid prescribing. In reality, APF functioned largely as an advocate for the interests of the Marketing Conspirators, not patients.

303. In practice, APF operated in close collaboration with the Marketing Conspirators. APF submitted grant proposals seeking to fund activities and publications suggested by the Marketing Conspirators. APF also assisted in marketing projects for the Marketing Conspirators.

304. The close relationship between APF and Marketing Conspirators demonstrates APF's clear lack of independence in its finances, management, and mission. APF's willingness to allow the Marketing Conspirators to control its activities and messages supports an inference that each Marketing Conspirator that worked with it was able to exercise editorial control over its publications.

305. In May 2012, the U.S. Senate Committee on Finance ("Senate Finance Committee") began investigating APF to determine the links, financial and otherwise, between the organization and manufacturers of opioid painkillers.

306. Within days of being targeted by the United States Senate's investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF then "cease[d] to exist, effective immediately."[156]

b. The AAPM's Role in Marketing Conspirators' Marketing of Opioids

307. The American Academy of Pain Medicine (AAPM), with the assistance, prompting, involvement and funding of the Marketing Conspirators, issued treatment guidelines

[156] https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups.

and sponsored and hosted CMEs essential to the Marketing Conspirators' marketing plans.

308. AAPM received over $2.2 million in funding since 2009 from the Marketing Conspirators and other drug manufacturers.

309. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California – or other resort locations.

310. AAPM describes the annual event as an "exclusive venue" for offering CMEs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Several of the Marketing Conspirators were members of the council and presented marketing programs to doctors who attended this annual event.

311. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids – for example 37 out of roughly 40 sessions at one conference alone addressed opioids.

312. AAPM's presidents have included top industry-supported KOLs including Dr. Portenoy, Dr. Webster, and Dr. Perry Fine. Dr. Webster was elected president of AAPM while he was under DEA investigation.

313. AAPM's staff understood that they and their industry funders were engaged in a common task. The Marketing Conspirators were able to influence AAPM through both their significant and regular financial support and the leadership of pro-opioid KOLs within the organization.

c. The Joint Commission's Role in Marketing Conspirators' Marketing of Opioids

314. The Joint Commission is an organization that establishes standards for treatment

and accredits healthcare organizations in the United States. The Marketing Conspirators, including Defendant Purdue, gave the Joint Commission misleading teaching materials and videos which emphasized what the Marketing Conspirators coined as the "under-treatment of pain," referenced pain as the "fifth vital sign" (the first and only unmeasurable/subjective vital sign) that must be monitored and treated, and encouraged the use of prescription opioids for chronic pain while minimizing the danger of addiction. These materials also called doctors' concerns about addiction "inaccurate and exaggerated."

315. In 2000, the Joint Commission printed a book for purchase by doctors as part of required continuing education seminars that cited studies claiming "there is no evidence that addiction is a significant issue when persons are given opioids for pain control." The book was sponsored by Defendant Purdue.

316. In 2001, the Joint Commission and the National Pharmaceutical Council (founded in 1953 and supported by the nation's major pharmaceutical companies[157]) collaborated to issue a 101-page monograph titled "Pain: Current understanding of assessment, management, and treatments." The monograph states falsely that beliefs about opioids being addictive are "erroneous":

> Societal issues that contribute to the undertreatment of pain include drug abuse programs and erroneous beliefs about tolerance, physical dependence, and addiction (see I.E.5). For example, some clinicians incorrectly assume that exposure to an addictive drug usually results in addiction.
>
> * * *
>
> b. Etiology, issues, and concerns
>
> Many medications produce tolerance and physical dependence, and some (e.g., opioids, sedatives, stimulants, anxiolytics, some muscle relaxants) may cause addiction in

[157] Funded by Johnson & Johnson, Purdue and Teva, among others.

> vulnerable individuals. Most experts agree that patients who undergo prolonged opioid therapy usually develop physical dependence but do not develop addictive disorders. In general, patients in pain do not become addicted to opioids. Although the actual risk of addiction is unknown, it is thought to be quite low. A recent study of opioid analgesic use revealed "low and stable" abuse of opioids between 1990 and 1996 despite significant increases in opioids prescribed. . . .
>
> Fear of causing addiction (i.e., iatrogenic addiction), particularly with opioid use, is a major barrier to appropriate pain management. This fear sometimes reflects a lack of understanding of the risk of addiction with therapeutic drug use. Although studies suggest that the risk of iatrogenic addiction is quite low (e.g., Perry and Heidrich, Zenz et al.), surveys indicate that clinicians often overestimate this risk.[158]

317. Additionally, the monograph recommends that "[p]ain . . . is assessed in all patients" and suggests that long-acting (*i.e.*, extended release) pain medications are superior and should be used whenever possible:

> Long-acting and sustained-release opioids are useful for patients with continuous pain, as they lessen the severity of end-of-dose pain and often allow the patient to sleep through the night. . . .
>
> * * *
>
> Administer opioids primarily via oral or transdermal routes, using long-acting medications when possible.[159]

318. As alleged above, however, such medications do not in fact last as long as promised, and, contrary to the monograph's claims, addiction risk is very high.

319. The Marketing Conspirators' infiltration and influence over the Joint Commission's standards and literature provided doctors with misleading information under the guise of objectivity.

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[158] *Pain: Current Understanding of Assessment, Management, and Treatments* 16-17 (Dec. 2001), http://www.npcnow.org/system/files/research/download/Pain-Current-Understanding-of-Assessment-Management-and-Treatments.pdf (footnotes and citations omitted).
[159] *Id*. at 38, 68 (Table 38).

320. Further, as more and more doctors migrated from private practice to integrated healthcare systems in the 2000s, treatment options were dictated by, among other things, the Joint Commission's guidelines.[160] Consistent with the guidelines, doctors who left pain untreated were viewed as demonstrating poor clinical skills and/or being morally compromised.[161]

d. The APA's Role in Marketing Conspirators' Marketing of Opioids

321. Founded in 2006, the Alliance for Patient Access ("APA") is a self-described patient advocacy and health professional organization that has styles itself as "a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care." It is run by Woodberry Associates LLC, a lobbying firm that was also established in 2006.[162] As of July 2019, the APA listed 30 "Associate Members and Financial Supporters," including Allergan, J&J, Teva, and Mallinckrodt. Prior lists included Endo, Purdue and others.

322. APA's board members have also directly received substantial funding from pharmaceutical companies.[163] For instance, board vice president Dr. Srinivas Nalamachu ("Nalamachu"), who practices in Kansas, received more than $800,000 from 2013 through 2015 from pharmaceutical companies—nearly all of it from manufacturers of opioids or drugs that treat opioids' side effects, including from Marketing Conspirators Endo, Insys, Purdue and Cephalon. Nalamachu's clinic was raided by FBI agents in connection with an investigation of Insys and its payment of kickbacks to physicians who prescribed Subsys. Other board members

[160] Lembke (2016), *supra* n.26, at 119.
[161] *Id*. at 42.
[162] Mary Chris Jaklevic, *Non-Profit Alliance for Patient Access Uses Journalists and Politicians to Push Big Pharma's Agenda*, Health News Rev. (Oct. 2, 2017),
[163] All information concerning pharmaceutical company payments to doctors in this paragraph is from ProPublica's Dollars for Docs database, https://projects.propublica.org/docdollars/.

include Dr. Robert A. Yapundich from North Carolina, who received $215,000 from 2013 through 2015 from pharmaceutical companies, including payments by defendants Cephalon and Mallinckrodt; Dr. Jack D. Schim from California, who received more than $240,000 between 2013 and 2015 from pharmaceutical companies, including Marketing Conspirators Endo, Mallinckrodt and Cephalon; Dr. Howard Hoffberg from Maryland, who received $153,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Purdue, Insys, Mallinckrodt and Cephalon; and Dr. Robin K. Dore from California, who received $700,000 between 2013 and 2015 from pharmaceutical companies.

323. Among its activities, APA issued a "white paper" titled "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse."[164] Among other things, the white paper criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user friendly, and of questionable efficacy:

> Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief medications elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal.
>
> * * *
>
> In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover, threatening and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives. . . .

[164] Pain Therapy Access Physicians Working Group, Prescription Pain Medication: Preserving Patient Access While Curbing Abuse, (Dec. 2013), http://1yh21u3cjptv3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2013/12/PT_White-Paper_Finala.pdf.

> We cannot merely assume that these programs will reduce prescription pain medication use and abuse.[165]

324. The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:

> Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements. . . . [I]t is not even certain that the regulations are helping prevent abuses.[166]

325. In addition, in an echo of earlier industry efforts to push back against what they termed "opiophobia," the white paper laments the stigma associated with prescribing and taking pain medication:

> Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can't get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong—or even criminal. . . . Physicians can face similar stigma from peers. Physicians in non- pain specialty areas often look down on those who specialize in pain management—a situation fueled by the numerous regulations and fines that surround prescription pain medications. [167]

326. In conclusion, the white paper states that "[p]rescription pain medications, and specifically the opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs." [168]

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[165] *Id*. at 4-5.
[166] *Id*. at 5-6.
[167] *Id*. at 6.
[168] *Id*. at 7.

327. The APA also issues "Patient Access Champion" financial awards to members of Congress, including 50 such awards in 2015. The awards were funded by a $7.8 million donation from unnamed donors. While the awards are ostensibly given for protecting patients' access to Medicare, and are thus touted by their recipients as demonstrating a commitment to protecting the rights of senior citizens and the middle class, they appear to be given to provide cover to and reward members of Congress who have supported the APA's agenda,

328. The APA also lobbies Congress directly. In 2015, the APA signed onto a letter supporting legislation proposed to limit the ability of the DEA to police pill mills by enforcing the "suspicious orders" provision of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §801 *et seq.* ("CSA" or "Controlled Substances Act"). The AAPM is also a signatory to this letter. An internal U.S. Department of Justice ("DOJ") memo stated that the proposed bill "could actually result in increased diversion, abuse, and public health and safety consequences"[169] and, according to DEA chief administrative law judge John J. Mulrooney ("Mulrooney"), the law would make it "all but logically impossible" to prosecute manufacturers and distributors, like the defendants here, in the federal courts.[170] The bill passed both houses of Congress and was signed into law in 2016.

e. The USPF's Role in Marketing Conspirators' Marketing of Opioids

329. The U.S. Pain Foundation ("USPF") was another Front Group with systematic connections and interpersonal relationships with the Marketing Conspirators. The USPF was one of the largest recipients of contributions from the Marketing Conspirators, collecting nearly $3

[169] Bill Whitaker, *Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress*, CBS News (Oct. 17, 2017), https://www.cbsnews.com/news/ ex-dea-agent-opioid-crisis-fueled-by- drug-industry-and-congress/.
[170] John J. Mulrooney, II & Katherine E. Legel, Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters, 101 Marquette L. Rev., 333, 346 (2017).

million in payments between 2012 and 2015 alone. The USPF was also a critical component of the Marketing Conspirators' lobbying efforts to reduce the limits on over-prescription. The U.S. Pain Foundation advertises its ties to the Marketing Conspirators, listing opioid manufacturers like Pfizer, Teva, Depomed, Endo, Purdue, McNeil *(i.e.*, Janssen), and Mallinckrodt as "Platinum," "Gold," and "Basic" corporate members.[171] Industry Front Groups like the American Academy of Pain Management, the American Academy of Pain Medicine, the American Pain Society, and PhRMA are also members of varying levels in the USPF.

330. The coordination of the APF and USPF (collectively the "pain foundations") with the Marketing Conspirators is discussed in greater detail below.

f. The AGS's Role in Marketing Conspirators' Marketing of Opioids

331. The American Geriatrics Society ("AGS") was another Front Group with systematic connections and interpersonal relationships with the Marketing Conspirators. AGS was a large recipient of contributions from the Marketing Conspirators, including Endo, Purdue and Janssen. AGS contracted with Purdue, Endo and Janssen to disseminate guidelines regarding the use of opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons*, hereinafter "2002 AGS Guidelines") and 2009 (Pharmacological Management of Persistent Pain in Older Persons,[172] hereinafter "2009 AGS Guidelines"). According to news reports, AGS has received at least $344,000 in funding from opioid manufacturers since 2009.[173] AGS's complicity with the Marketing Conspirators is evidenced by the fact that AGS internal discussions in August 2009 reveal that it did not want to receive-up front funding from drug

[171] Fueling an Epidemic, supra note 154.
[172] Pharmacological Mgmt. of Persistent Pain in Older Persons, 57 J. Am. Geriatrics Soc'y 1331, 1339, 1342 (2009).
[173] John Fauber & Ellen Gabler, Narcotic Painkiller Use Booming Among Elderly, Milwaukee J. Sentinel (May 30, 2012) https://www.medpagetoday.com/geriatrics/painmanagement/32967.

companies, which would suggest drug company influence, but would instead accept commercial support to disseminate pro-opioid publications.

332. The 2009 AGS Guidelines recommended that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy." The panel made "strong recommendations" in this regard despite "low quality of evidence" and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse.[174] These Guidelines further recommended that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." These recommendations are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited over 1,833 times in Google Scholar (which allows users to search scholarly publications that would have been relied on by researchers and prescribers) since their 2009 publication and as recently as 2017.

333. Representatives of the Marketing Conspirators, often at informal meetings at conferences, suggested activities, lobbying efforts and publications for AGS to pursue. AGS then submitted grant proposals seeking funding for these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

334. Members of AGS Board of Directors were doctors who were on the Marketing Conspirators' payrolls, either as consultants or speakers at medical events. As described below, many of the KOLs also served in leadership positions within the AGS.

[174] 2009 AGS Guidelines at 1342.

3. The Marketing Conspirators' Corruption of Scientific Literature to Further Their Deceptive Marketing of Opioids

335. Rather than actually test the safety and efficacy of opioids for long-term use, the Marketing Conspirators led physicians, patients, and health plan administrators to believe that such tests had already been performed.

336. The Marketing Conspirators created a body of false, misleading, and unsupported medical and popular literature about opioids that: (i) understated the risks and overstated the effectiveness of long-term opioid use; (ii) appeared to be the result of independent, objective research; and (iii) was likely to shape the perceptions and purchasing decisions of prescribers, patients, and health care payors. This literature was, in fact, marketing material intended to persuade doctors, patients, and third-party payors that the benefits of long-term prescription opioid use outweighed the risks.

337. To accomplish their goal, the Marketing Conspirators – sometimes through third-party consultants and/or front groups – commissioned, edited, and arranged for the placement of misleading favorable articles in academic journals.

338. The Marketing Conspirators' plans for these materials did not originate in the departments within the Marketing Conspirators' organizations that were responsible for research, development, or any other area that would have specialized knowledge about the drugs and their effects on patients. Rather, they originated in Marketing Conspirators' marketing departments and with Marketing Conspirators' marketing and public relations consultants.

339. One commentator noted the following regarding the pharmaceutical industry generally: "To give you an idea of how much the drug industry values sales and advertising, the

fact is that Big Pharma spends more on that than on actual drug research and development."[175]

340. In these marketing materials, the Marketing Conspirators or their surrogates often claimed to rely on "data on file" or presentation posters, neither of which was subject to peer review or other scientific safeguards of reliability. Still, the Marketing Conspirators presented these materials to the medical community as scientific articles or studies, despite the fact that Marketing Conspirators' materials were not based on reliable data or the use of normal practices of scientific safeguards to assure reliability and were not subject to the scrutiny of others who are experts in the same field.

341. The Marketing Conspirators also made sure that favorable articles were disseminated and cited widely in the medical literature, even when Marketing Conspirators knew that the articles distorted the significance or meaning of the underlying study.

342. For example, the Marketing Conspirators frequently cited a 1980 item in the well-respected New England Journal of Medicine – J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 (2) New Eng. J. Med. 123 (1980) ("Porter & Jick Letter") – in a manner that makes it appear that the item reported the results of a peer reviewed study. The Marketing Conspirators and those acting on their behalf failed to reveal that this "article" is actually a letter to the editor, not a study, much less a peer-reviewed study. The letter merely states that the authors examined their files of hospitalized patients who had received opioids, and summarized what they found. The Porter & Jick Letter is reproduced in its entirety below:

[175] Jake Novak, *Big Pharma's Opioid Mess is About to Hit the Industry – Hard*, CNBC (Oct. 18, 2017), *available at* https://www.cnbc.com/2017/10/18/how-opioid-crisis-will-crush-big-pharma-commentary.html.

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

343. The patients referred to in the Porter & Jick Letter were all treated prior to the letter, which was published in 1980. Because of standards of care prior to 1980, the treatment of those patients with opioids was limited to acute or end-of-life situations, not long-term use of opioids for chronic pain.

344. The letter notes that, when these patients' records were reviewed, the authors found almost no references to signs of addiction, though there is no indication that caregivers were instructed to look for, assess, or document signs of addiction. Nor is there any indication whether the patients were monitored after they were discharged from the hospital.

345. None of these serious limitations were disclosed when the Marketing Conspirators and those acting on their behalf cited the letter, typically as the *sole scientific support* for the proposition that opioids are safe and rarely addictive. In fact, Dr. Jick later complained that his letter had been distorted and misused.

346. The Marketing Conspirators' campaign of misinformation has continued in

subsequent years and even through the present. For example, a Purdue-funded study in 2017 in the Journal of Managed Care & Specialty Pharmacy stated: "[N]early 100 million Americans live with chronic pain.... For moderate to severe pain, opioids can provide significant symptom relief."[176] The study made no reference to the risks of using opioids or the difference in both efficacy and risk between short-term and long-term use.

347. The Marketing Conspirators wrongfully worked to not only create and promote favorable studies in the literature, but also to discredit or suppress negative information about prescription opioids. The Marketing Conspirators' studies and articles often targeted articles that contradicted Marketing Conspirators' claims or raised concerns about chronic opioid therapy.

348. In order to do so, the Marketing Conspirators – often with the help of third-party consultants – used a broad range of media to get their message out, including negative review articles, letters to the editor, commentaries, care-study reports, and newsletters.

349. The Marketing Conspirators' strategy – to plant and promote supportive literature and then to cite the pro-opioid evidence in their promotional materials, while failing to disclose evidence that contradicted those claims – resulted in egregiously misleading marketing and promotion. The strategy was intended to, and did, distort prescribing patterns by distorting the truth regarding risks and benefits of prescription opioids for long-term pain relief.

350. The Marketing Conspirators' misleading statements and scientific literature were directly or indirectly disseminated to patients, physicians, and others including third-party payors, PBMs and other health plan administrators.

351. The Marketing Conspirators' promotion of opioids via false, deceptive,

[176] Noam Kirson *et al.*, *The Economic Burden of Opioid Abuse: Updated Findings*, Journal of Managed Care & Specialty Pharmacy, at 427 (April 2017), *available at* http://www.jmcp.org/doi/pdf/10.18553/jmcp.2017.16265.

misleading and incomplete statements in the medical and scientific literature did not stop at the physician level but also was aimed at, and directly and indirectly received by, other participants in the opioid marketing process including third-party payers and PBMs. For example, as part of the formulary listing process described below, manufacturer representatives submitted written materials, such as formulary dossiers and other written descriptions of the drugs, which in turn incorporated misleading date concerning the particular drug. Manufacturer representatives also disseminated other false, misleading and unsupported medical literature about opioids to third-party payors, PMBs and others, including so-called "studies" and other statements, as alleged more fully herein that, in turn, relied on highly misleading statements concerning the alleged benefits and safety of opioids such as the Portenoy and Porter & Jick materials discussed above.

4. The Marketing Conspirators' Misuse of Treatment Guidelines and Consensus Statements to Further Their Deceptive Marketing or Opioids

352. "Treatment guidelines" and consensus statements have been particularly important in securing acceptance for long-term opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors targeted by the Marketing Conspirators, who generally are not experts and have no special training in the treatment of chronic pain.

353. Treatment guidelines and consensus statements not only directly inform doctors' prescribing practices, but also are cited throughout scientific literature and are relied on by third-party payors and PBMs in determining whether prescription opioids can be listed as approved pain relievers and whether they should pay for treatments for specific indications.

354. Treatment guidelines and consensus statements also were disseminated directly or indirectly to third party payors and PBMs and were part of the Marketing Conspirators' marketing to formularies.

a. The Federation of State Medical Boards Was a Target of the Marketing Conspirators' Deceptive Marketing of Opioids

355. The Federation of State Medical Boards ("FSMB") is a trade group representing the 70 medical and osteopathic boards in the United States. The FSMB develops guidelines that serve as the basis for model policies with the stated goal of improving medical practice. State boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians. The Pennsylvania State Boards of Medicine and Osteopathic Medicine are among the boards comprising the FSMB.

356. Defendants Purdue, Endo, Cephalon and Mallinckrodt have provided grants to the FSMB to finance opioid-specific programs.[177]

357. Since 1998, the FSMB has been developing state medical board policies for the use of opioids to treat pain. The 1998 version, titled *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("1998 Guidelines"), was produced "in collaboration with pharmaceutical companies." With the influence of the Marketing Conspirators, the 1998 Guidelines provided not that opioids could be appropriate in limited cases after other pain treatments had failed, but that opioids were "essential" for treatment of chronic pain, including as a first prescription option.

358. A 2004 version of the 1998 Guidelines, and a 2007 book titled *Responsible Opioids Prescribing. A Physician's Guide* ("Responsible Opioids Prescribing") by Dr. Scott M. Fishman ("Fishman"), also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including in the City of Allentown.

[177] Ltr. from FSMB to U.S. Senate regarding Senate review of opioid abuse issues, June 8, 2012, at pg. 11-14, *available at* https://assets.documentcloud.org/documents/3109089/FSMB-Response-Letter-to-US-Senate.pdf.

359. After Dr. Fishman's guide was adopted as a model policy, the FSMB reportedly asked Purdue for $100,000 to help pay for printing and distribution. FSMB disseminated the guide to 700,000 practicing doctors, with 163,131 of these copies being distributed by state medical boards.[178]

360. The guide's clear purpose is to deceive prescribers regarding the purported undertreatment of pain and falsely assure them that opioid therapy is an appropriate treatment for chronic, non-cancer pain (emphases added):

> - Pain management is integral to good medical practice and for all patients;
> - ***Opioid therapy to relieve pain and improve function is a legitimate medical practice for*** acute and ***chronic pain of*** both cancer and ***noncancer origins***;
> - ***Patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient***.
>
> * * *
>
> ***Four key factors contribute to the ongoing problem of under-treated pain***:
>
> 1. Lack of knowledge of medical standards, current research, and clinical guidelines for appropriate pain treatment;
>
> 2. The perception that prescribing adequate amounts of opioids will result in unnecessary scrutiny by regulatory authorities;
>
> 3. ***Misunderstanding of addiction and dependence***; and
>
> 4. Lack of understanding of regulatory policies and processes.

361. The guide also purports to offer "professional guidelines" that will "easily and efficiently" allow physicians to manage that risk and "minimize the potential for abuse." Indeed, it states that even for those patients assessed to have risk of substance abuse, "it does not mean that opioid use will become problematic or that opioids are contraindicated," just that physicians

[178] *Id.* at pg. 19.

should use additional care in prescribing.

362. The guide further warns physicians to "[b]e aware of the distinction between pseudoaddiction and addiction" and instructs that behaviors such as "[r]equesting [drugs] by name," "[d]emanding or manipulative behavior," "[o]btaining opioid drugs from more than one physician" and "[h]oarding opioids," are just signs of "pseudoaddiction."

363. It defines "Physical Dependence" as an acceptable result of opioid therapy not to be equated with addiction and states that while "[i]t may be tempting to assume that patients with chronic pain and a history of recreational drug use who are not adherent to a treatment regimen are abusing medications," there could be other acceptable reasons for non-adherence.

364. The guide, which became the seminal authority on opioid prescribing for the medical profession, dramatically overstated the safety and efficacy of opioids and understated the risk of opioid addiction.

365. This heightened focus on the under-treatment of pain was a concept designed by the Marketing Conspirators to sell opioids. The FSMB actually issued a report calling on medical boards to punish doctors for inadequately treating pain.[179] Among the drafters of this policy was Dr. Haddox.

366. Having influenced the 1998 Guidelines, the Marketing Conspirators also used them to help convey the alarming message that "*under-treatment of pain" could result in official discipline*, and that no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented.

367. The successful targeting of the FSMB by the Marketing Conspirators and their agents turned doctors' fear of discipline on its head: doctors, who used to believe that they would

[179] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012, at A1.

be disciplined if their patients became addicted to opioids, were taught instead that they would be reprimanded if they failed to prescribe opioids to their patients with chronic pain.

368. In 2012 and again in 2017, the guides and the sources of their funding became the subject of a Senate investigation.

369. On June 8, 2012, the FSMB submitted a letter to the Senate Finance Committee concerning the Senate's investigation into the abuse and misuse of opioids.[180] While the letter acknowledged the escalation of drug abuse and related deaths resulting from prescription painkillers, the FSMB continued to focus on the "serious and related problem" that "[m]illions of Americans suffer from debilitating pain – a condition that, for some, can be relieved through the use of opioids." Among other things, the letter stated, "studies have concluded that both acute pain and chronic pain are often under-treated in the United States, creating serious repercussions that include the loss of productivity and quality of life." The letter cited no such studies. The letter also confirmed that the FSMB's "Responsible Opioid Prescribing: A Physician's Guide" had been distributed in each of the 50 states and the District of Columbia.

370. In addition, the FSMB letter disclosed payments the FSMB received from organizations that develop, manufacture, produce, market or promote the use of opioid-based drugs from 1997 to 2011, including the payments received from Marketing Conspirators as reflected in the chart below:

[180] June 8, 2012 Letter from Federation of State Medical Boards to U.S. Senators Max Baucus and Charles Grassley.

Company	Fiscal Year	Amount
Purdue	2001	$38,324.56
	2002	$10,000.00
	2003	$85,180.50
	2004	$87,895.00
	2005	$244,000.00
	2006	$207,000.00
	2007	$50,000.00
	2008	$100,000.00
	Total Purdue Payments	$822,400.06
Endo	2007	$40,000.00
	2008	$100,000.00
	2009	$100,000.00
	2011	$125,000.00
	2012	$46,620.00
	Total Endo Payments	$371,620.00
Cephalon	2007	$30,000.00
	2008	$100,000.00
	2011	$50,000.00
	Total Cephalon Payments	$180,000.00
Mallinckrodt	2011	$100,000.00
	Total Mallinckrodt Payments	$100,000.00

371. The letter also disclosed payments of $40,000 by Endo and $50,000 by Purdue to directly fund the production of "Responsible Opioid Prescribing."

b. The American Academy of Pain Medicine/American Pain Society Guidelines' Role in Marketing Conspirators' Deceptive Marketing of Opioids

372. The AAPM and APS are professional medical societies, each of which received substantial funding from the Marketing Conspirators.

373. In 1997, AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.[181] The chair of the committee that issued the statement, KOL Dr. Haddox, was at the time a paid

[181] *The Use of Opioids for the Treatment of Chronic Pain*, APS & AAPM (1997), *available at* http://opi.areastematicas.com/generalidades/OPIOIDES.DOLORCRONICO.pdf.

speaker for Defendant Purdue. The sole consultant to the committee was KOL Dr. Portenoy. The consensus statement, which also formed the foundation of the Marketing Conspirator-influenced 1998 Guidelines, was published on the AAPM's website and distributed to new AAPM members until 2012.

374. AAPM and APS issued their own guidelines in 2009 ("2009 Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the twenty-one panel members who drafted the 2009 Guidelines, including KOLs Dr. Portenoy and Dr. Fine, received support from Defendants Janssen, Cephalon, Endo, Purdue, and Mallinckrodt.

375. The 2009 Guidelines promoted opioids as "safe and effective" for treating chronic pain, and concluded that the risk of addiction is manageable for patients regardless of past abuse histories. The 2009 Guidelines have been a particularly effective channel for Marketing Conspirators and have influenced not only treating physicians, but also the body of scientific evidence addressing opioids. They were reprinted in the *Journal of Pain*, have been cited hundreds of times in academic literature, were and are available online, and were made available in Allentown as well as nationwide.

376. The Marketing Conspirators widely cited and promoted the 2009 Guidelines as part of their deceptive marketing, without disclosing the lack of evidence to support their conclusions.

c. Guidelines that Did Not Receive the Marketing Conspirators' Support

377. The extent of the Marketing Conspirators' influence on treatment guidelines is demonstrated by the fact that independent guidelines – the authors of which did not accept drug-company funding – reached very different conclusions.

378. For example, the 2012 *Guidelines for Responsible Opioid Prescribing in Chronic*

Non-Cancer Pain, issued by the American Society of Interventional Pain Physicians ("ASIPP"), warned that the "recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it."[182]

379. ASIPP's Guidelines further advise that "therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain."[183]

380. ASIPP recommends long-acting opioids in high doses in only "specific circumstances with severe intractable pain," and only when coupled with "continuous adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvements in physical and functional status and minimal adverse effects."[184]

381. Similarly, the 2011 *Guidelines for the Chronic Use of Opioids*, issued by the American College of Occupational and Environmental Medicine, recommended against the "routine use of opioids in the management of patients with chronic pain," findings "at least moderate evidence that harms and costs exceed benefits based on limited evidence."[185]

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[182] Laxmaiah Manchikanti, *et al.*, American Society of Interventional Pain Physicians (ASIPP), *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain*, at pg. 85 (2012), *available at* http://painphysicianjournal.com/2012/july/2012;15;81-866.pdf.
[183] http://painphysicianjournal.com/2012/july/2012;15;81-866.pdf, at pg. 85.
[184] http://painphysicianjournal.com/2012/july/2012;%2015;S67-S116.pdf. at pg. S68.
[185] American College of Occupational and Environmental Medicine's Guidelines for the Chronic Use of Opioids, at pg. 3, 10 (2011), *available at* https://www.nhms.org/sites/default/files/Pdfs/ACOEM%202011-Chronic%20Pain%20Opioid%20.pdf.

382. Further, the *Clinical Guidelines on Management of Opioid Therapy for Chronic Pain*, issued in 2010 by the U.S. Department of Veterans Affairs ("VA") and Department of Defense ("DOD"), notes that their review revealed a lack of solid evidence-based research on the efficacy of long-term opioid therapy.[186]

5. The Marketing Conspirators' Misuse of Continuing Medical Education Programs to Further Their Deceptive Marketing

383. A CME is a professional education program provided to doctors. CMEs are analogous to continuing legal education programs provided to attorneys. Doctors are required to attend a certain number – and often type – of CME programs each year as a condition of licensure.

384. These programs are delivered in person (often in connection with professional organizations' conferences), online, or via written publications.

385. Doctors rely on CME's not only to satisfy licensing requirements, but also to obtain information on new developments in medicine or to deepen their knowledge in specific areas of practice.

386. CMEs are often taught by KOLs who are highly respected in their fields, and are thought to reflect these physicians' medical expertise. Thus, CMEs can be especially influential with doctors.

387. The countless doctors and other health care professionals who attend or view accredited CMEs constituted an enormously important audience for opioid education.

388. As one target, the Marketing Conspirators aimed to reach general practitioners, whose broad area of practice and lack expertise and specialized training in pain management

[186] Management of Opioid Therapy for Chronic Pain Working Group, VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain (May 2010), *available at* http://www.healthquality.va.gov/guidelines/Pain/cot/COT_312_Full-er.pdf.

made them particularly dependent upon CMEs. As result, general practitioners were especially susceptible to the Marketing Conspirators' marketing.

389. The Marketing Conspirators sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the biased messages described throughout this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focused on opioids to the exclusion of alternative treatment, inflated the benefits of opioids, and frequently omitted or downplayed their risks and adverse effects.

390. The American Medical Association ("AMA") had recognized that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interest could influence the availability and/or content" of the programs and urges that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interest in the education subject matter."[187]

391. The U.S. General Accounting Office's December 2003 Report to Congressional Requesters confirms that Purdue funded "pain management educational courses" that taught the new standard of care for treating pain. It further revealed that Purdue disseminated educational materials on pain management, which "'facilitated [Purdue's] access to hospitals to promote OxyContin.'"[188]

392. On information and belief, physicians and others involved in health plan administration, such as pharmacy benefit managers, formulary personnel and others in Plaintiff's Community and nationwide, attended or reviewed the Marketing Conspirators' sponsored CMEs

[187] Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass'n at pg. 1 (Nov. 2011) *available at* http://www.msma.org/uplouds/6/2/5/3/62530417/ama_ethical_oponion_9.0115_financial_relationships_with_in_cme.doc.

[188] *Supra*, *Who Is Responsible*, *supra* n.35; U.S. General Accounting Office, GAO-04-110, *Prescription Drugs, OxyContin Abuse and Diversion and Efforts to Address the Problem* (Dec. 2003), http://www.gao.gov/new.items/d04110.pdf).

as the use and abuse of prescription opioids skyrocketed.

393. When sponsoring CME programs provided by Front Groups like APF, AAPM and others, the Marketing Conspirators expected instructors to deliver messages favorable to the Marketing Conspirators, as these organizations were dependent on the Marketing Conspirators for funding and other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Marketing Conspirator-driven content in these CMEs had a direct, immediate, and inherent effect on prescribers' views of opioids.

394. Producers of CMEs and Marketing Conspirators measure the effects of CMEs on prescribers' views on opioids, and prescribers' receptivity to and absorption of specific messages, helping Marketing Conspirators sharpen their CME marketing campaign going forward.

C. The Marketing Conspirators Targeted a Broad Audience to Induce PBMs and Others to Authorize Payment of Prescription Opioids

395. The Marketing Conspirators' misleading marketing was directly and indirectly disseminated to third-party payors, PBMs, local governments, and other health plan administrators, with the intention that third-party payors, PBMs, local governments, and other health plan administrators rely upon it.

1. The Marketing Conspirator's Strategy for Pharmacy Benefit Managers

396. A PBM is an administrator of prescription drug programs for private and public health plans, including self-insured companies and government entities. PBMs have acted as middlemen in prescription drug benefits transactions in the United States since the mid-1990s. Initially, they merely handled claims transactions. Over time, however, they began handling

more aspects of the U.S. pharmaceutical reimbursement process including "pharmacy network administration, formulary design and management, manufacturer rebate negotiation, drug utilization review (to determine whether a patient's prescriptions may interact), physician communication and education (including formulary compliance incentives), mail-order pharmacy services, generic substitution plans, and assumption of risk."

397. PBMs (as well as third party payors and health plan administrators, in some instances) prepare and administer a "formulary," which is a list of drugs that are approved for coverage by the health plan. In general, in order for a drug to be listed on the formulary, it must be assessed by the PBM (or third party payor or health plan administrator, in some instances) for clinical safety, efficacy, and where applicable, cost effectiveness. In designing formularies, a PBM generally uses a Pharmacy and Therapeutics Committee comprised of clinical pharmacists and physicians who review the drugs in each therapeutic class and the evidence of each drug's effectiveness, safety, contra-indications and costs.[189]

398. The committee generally evaluates the clinical utility of the drug for a health plan based on information in the medical literature and clinical content about the product supplied by the manufacturer. This content is approved for distribution to the plan by senior executives representing legal, regulatory, and medical functions.

399. According to the American Pharmacists Association, PBMs are primarily responsible for developing and maintaining the formulary.[190]

400. In 2007, the function of PBMs changed from "simply processing prescription

[189] Patricia M. Danzon, PhD, *PBM Compensation and Fee Disclosure*, 2014 ERISA Advisory Council, at pg. 1 (2014), *available at* https://www.dol.gov/sites/default/files/ebsa/about-ebsa/about-us/erisa-advisory/council/ACDanzon061914.pdf.
[190] *Pharmacy Benefit Management*, American Pharmacists Association (2009), *available at* https://www.pharmacist.com/sites/default/files/files/Profile_24_PBM_SDS_FINAL_090707.pdf.

transactions to managing the pharmacy benefit for health plans."[191] PBMs also created a formulary that encouraged or even required "health plan participants to use preferred formulary products to treat their conditions." [192]

401. "PBMs are the 800-pound gorillas of pharmaceutical reimbursement."[193] According to published estimates, over 95% of Americans with health benefits receive drug coverage through a PBM.[194] As of 2016, PBMs managed pharmacy benefits for 266 million Americans.[195] Because such a large percentage of Americans are covered by these PBMs, formulary status can greatly influence a manufacturer's sales of a drug.[196] Indeed, the commercial success of a drug in the U.S. depends in significant part on the manufacturer's success in placing its drug on as many formularies as possible.

402. Drug manufacturers are acutely aware of the powerful role of PBMs in the marketplace and the need to obtain approval of PBMs to successfully place a drug on any given formulary. The Marketing Conspirators were, at all times relevant hereto, aware that PBM approval was important to the commercial success of their pharmaceutical products.

403. Drug manufacturers including Marketing Conspirators maintain a team of sales personnel, sometimes called National Account Managers ("NAMs") whose responsibility is to influence and negotiate placement of the particular drug on the formulary, and to oversee and

[191] Allison Dabbs Garrett *et al.*, *Leveling the Playing Field in the Pharmacy Benefit Management Industry*, 42 Valparaiso University Law Review 1, at pg. 34 (Fall 2007), *available at* http://scholar.valpo.edu/cgi/viewcontent/cgi?article=1131&context=vulr.
[192] *Id.*
[193] *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 71 (D. Mass 2005).
[194] Federal Trade Commission, Ltr. to Senator Richard L. Brown, North Dakota Senate, at pg. 4 (March 8, 2005), *available at* http://www.ftc.gov/os/2005/03/050311northdakotacomnts.pdf.
[195] *That's What PBMs Do*, Pharmaceutical Care Management Association (March 14, 2016), *available at* https://www.youtube.com/watch?v=gfrJPsPsFYI.
[196] J. Shepherd, *Is More Information Always Better*? Mandatory Disclosure Regulations in the Prescription Drug Market, Emory University School of Law, Legal Studies Research Paper Series, Research Paper No. 13-245, at pg. 8 (March 2013), *available at* http://ssrn.com/abstract=2234212.

assist in making submissions regarding the various attributes of the particular drug, including the drug's alleged benefits and risks.

404. Obtaining placement of a drug on a formulary generally involves a combination of verbal and written communications between sales personnel (including NAMs) of the manufacturer and the third-party payor or PBM. The manufacturer's team typically meets with the formulary director or his or her designee to discuss the nature, safety and efficacy of the drug, and financial information including the costs, discounts, and other relevant contractual issues. The manufacturer's representatives may also make a written presentation, such as a "slide" presentation, as well as a clinical presentation where a clinical expert, such as a medical science liaison, presents information to the clinical evaluators at the third-party payor or PBM relating to the safety and efficacy of the drugs proposed to be listed.

405. The drug manufacturer may also prepare and disseminate a formulary "dossier," which describes the drug, the clinical evidence relating to safety and effectiveness, the price, the cost-effectiveness and other aspects of the drug.

406. Further, if a third-party payor or PBM finds that a drug has clinical, financial, or other advantage over competing drugs, that drug may be given a "preferred status" on its formulary, which is a higher preference compared to other drugs. Third-party payors or PBMs place approved drugs on their formularies in tiers, ranging from I to V. Tier I drugs are most preferred by third-party payors and PBMs because they are usually the least expensive for the third-party payor or PBM. As the tier level increases, so does the co-payment that the consumer is typically required to pay.

407. Drug manufacturers often offset those increased costs by offering co-pay coupons, with the sole objective to increase the sales of their respective drugs. Among other

things, manufacturers' use of coupons also helps enable the manufacturer to both market and sell more of its product by offsetting the costs directly by the consumer.

408. By directly and indirectly promoting opioids as safe and effective for long-term use using false and misleading statements, the Marketing Conspirators influenced third-party payors and PBMs in the placement of opioids on their formularies and in paying or reimbursing for opioid prescriptions purely for financial gain.

409. The Marketing Conspirators' deceptive and misleading marketing practices were widespread and succeeded in increasing the number of opioid prescriptions written and filled, both in Pennsylvania and nationwide. Because the Marketing Conspirators misstated and withheld material information about the true safety and efficacy of opioids, third-party payors and PBMs, among others, did not have sufficiently complete information to make informed decisions regarding the safety and efficacy of prescription opioids and the listing of those drugs on their prescription drug formularies or those of their customers.

410. During the relevant period covered by the Complaint, neither the City of Allentown nor the PBMs serving Allentown's residents were aware of the deceptive nature of the Marketing Conspirators' marketing activities, and the City and the PBMs paid for or reimbursed prescriptions filled on behalf of plan participants.

411. Third-party payors and PBMs were subject to and influenced by the Marketing Conspirators' misrepresentations and omissions, including those regarding the purported safety and efficacy of prescription opioids, which in turn influenced the number of prescription opioids which they paid for or reimbursed. Third-party payors and PBMs and their pharmacy and therapeutic committees were influenced by the Marketing Conspirators' misrepresentations of opioids' safety and efficacy when approving and/or placing opioids on formularies. Third-party

payors and PBMs were influenced by the Marketing Conspirators' misrepresentations of opioids' safety and efficacy in reimbursing and/or paying for prescriptions of opioids on behalf of their members.

412. Upon information and belief, PBMs servicing the residents of Allentown were subjected to the Marketing Conspirators' deceptive and misleading marketing activities, including misrepresentations and omissions about the purported safety and efficacy of opioids.

413. Due to these activities, the PBMs approved the prescription opioids of Defendants Purdue, Cephalon, Endo, Actavis, and Mallinckrodt for inclusion on the City's drug formulary and for which the City's paid or reimbursed substantial sums. Inclusion of prescription opioids on these formularies led to the use of these Defendants' prescription opioids by City employees.

414. Moreover, the failure of Defendants Purdue, Cephalon, Endo, Actavis, and Mallinckrodt to adequately inform the City of Allentown of that the use of prescription opioids for chronic pain was dangerous and likely to lead to abuse, misuse, and addiction (among other side-effects), and their false and misleading promotion of the efficacy of opioids over competing, safer non-opioid pain relievers, caused the City of Allentown itself to pay for or approve payment for prescription opioids, which it would otherwise not have.

415. The actions of Defendants Purdue, Cephalon, Endo, Actavis, and Mallinckrodt were a substantial factor in causing Allentown to pay for opioids for chronic pain in the quantities and amounts that it did.

2. The Evidence of Fraudulent and Illegal Marketing by Insys

416. The insidious nature of the Marketing Conspirators' misconduct is illustrated by the recently discovered evidence of fraudulent and illegal marketing by Insys.

417. Insys obtained FDA approval for Subsys in 2012 for "management of

breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain." Under FDA rules, Insys could only market Subsys for this use. Subsys consists of the highly addictive narcotic, fentanyl, administered via a sublingual (under the tongue) spray, which provides rapid-onset pain relief. It is in the class of drugs described as Transmucosal Immediate-Release Fentanyl ("TIRF").

418. To reduce the risk of abuse, misuse, and diversion, the FDA instituted a Risk Evaluation and Mitigation Strategy ("REMS") for Subsys and other TIRF products, such as Cephalon's Actiq and Fentora. The purpose of REMS was to educate "prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose" for this type of drug and to "ensure safe use and access to these drugs for patients who need them."[197] Prescribers must enroll in the TIRF REMS before writing a prescription for Subsys.

419. Since its launch, Subsys has been an extremely expensive medication, and its price continues to rise each year. Depending on a patient's dosage and frequency of use, a month's supply of Subsys could cost in the thousands of dollars.

420. Due to its high cost, in most instances prescribers must submit Subsys prescriptions to insurance companies or health benefit payors for prior authorization to determine whether they will pay for the drug prior to the patient attempting to fill the prescription. According to the U.S. Senate Homeland Security and Governmental Affairs Committee Minority Staff Report ("Staff Report"), the prior authorization process includes "confirmation that the patient had an active cancer diagnosis, was being treated by an opioid (and, thus, was opioid

[197] Press Release, U.S. Food & Drug Admin., FDA Approves Shared System REMS for TIRF Products (Dec. 29, 2011).

tolerant), and was being prescribed Subsys to treat breakthrough pain that the other opioid could not eliminate. If any one of these factors was not present, the prior authorization would be denied . . . ."[198]

421. These prior authorization requirements proved to be daunting. Subsys received reimbursement approval in only approximately 30% of submitted claims. In order to increase approvals, Insys created a prior authorization unit, called the Insys Reimbursement Center ("IRC"), to obtain approval for Subsys reimbursements. This unit employed a number of fraudulent and misleading tactics to secure reimbursements, including falsifying medical histories of patients, falsely claiming that patients had cancer, and providing misleading information to insurers and payors regarding patients' diagnoses and medical conditions.

422. Subsys has proved to be extremely profitable for Insys. Insys made approximately $330 million in net revenue from Subsys in 2015 alone. Between 2013 and 2016, the value of Insys stock rose 296%.

423. Since its launch in 2012, Insys aggressively worked to grow its profits through fraudulent, illegal, and misleading tactics, including its reimbursement-related fraud. Through its sales representatives and other marketing efforts, Insys deceptively promoted Subsys as safe and appropriate for uses such as neck and back pain, without disclosing the lack of approval or evidence for such uses, and misrepresented the appropriateness of Subsys for treatment of those conditions. It implemented a kickback scheme wherein it paid prescribers for fake speakers' programs in exchange for prescribing Subsys. All of these fraudulent and misleading schemes had the effect of pushing Insys's dangerous opioid onto patients who did not need it.

424. Insys incentivized its sales force to engage in illegal and fraudulent conduct.

[198] Fueling an Epidemic, supra note 154.

Many of the Insys sales representatives were new to the pharmaceutical industry and their base salaries were low compared to industry standard. The compensation structure was heavily weighted toward commissions and rewarded reps more for selling higher (and more expensive) doses of Subsys, a "highly unusual" practice because most companies consider dosing a patient-specific decision that should be made by a doctor.[199]

425. The Insys "speakers program" was perhaps its most widespread and damaging scheme. A former Insys salesman, Ray Furchak, alleged in a *qui tam* action that the sole purpose of the speakers program was "in the words of his then supervisor Alec Burlakoff, 'to get money in the doctor's pocket.'" Furchak went on to explain that "[t]he catch . . . was that doctors who increased the level of Subsys prescriptions, and at higher dosages (such as 400 or 800 micrograms instead of 200 micrograms), would receive the invitations to the program—and the checks."[200] It was a pay-to-prescribe program.

426. Insys's sham speaker program and other fraudulent and illegal tactics have been outlined in great detail in indictments and guilty pleas of Insys executives, employees, and prescribers across the country, as well as in a number of lawsuits against the company itself.

427. In May of 2015, two Alabama pain specialists were arrested and charged with illegal prescription drug distribution, among other charges. The doctors were the top prescribers of Subsys, though neither were oncologists. According to prosecutors, the doctors received illegal kickbacks from Insys for prescribing Subsys. Both doctors had prescribed Subsys to treat neck, back, and joint pain. In February of 2016, a former Insys sales manager pled guilty to conspiracy to commit health care fraud, including engaging in a kickback scheme in order to

[199] *Id*.
[200] Roddy Boyd, Insys Therapeutics and the New 'Killing It'", S. Investigative Reporting Found., The Investigator, (Apr. 24, 2015), http://sirf-online.org/2015/04/24/the-new-killing-it/.

induce one of these doctors to prescribe Subsys. The plea agreement states that nearly all of the Subsys prescriptions written by the doctor were off-label to non-cancer patients. In May of 2017, one of the doctors was sentenced to 20 years in prison.

428. In June of 2015, a nurse practitioner in Connecticut described as the state's highest Medicare prescriber of narcotics, pled guilty to receiving $83,000 in kickbacks from Insys for prescribing Subsys. Most of her patients were prescribed the drug for chronic pain. Insys paid the nurse as a speaker for more than 70 dinner programs at approximately $1,000 per event; however, she did not give any presentations. In her guilty plea, the nurse admitted receiving the speaker fees in exchange for writing prescriptions for Subsys.

429. In August of 2015, Insys settled a complaint brought by the Oregon Attorney General. In its complaint, the Oregon Department of Justice cited Insys for, among other things, misrepresenting to doctors that Subsys could be used to treat migraine, neck pain, back pain, and other uses for which Subsys is neither safe nor effective, and using speaking fees as kickbacks to incentivize doctors to prescribe Subsys.

430. In August of 2016, the State of Illinois sued Insys for similar deceptive and illegal practices. The Complaint alleged that Insys marketed Subsys to high-volume prescribers of opioid drugs instead of to oncologists whose patients experienced the breakthrough cancer pain for which the drug is indicated. The Illinois Complaint also details how Insys used its speaker program to pay high volume prescribers to prescribe Subsys. The speaker events took place at upscale restaurants in the Chicago area, and Illinois speakers received an "honorarium" ranging from $700 to $5,100, and they were allowed to order as much food and alcohol as they wanted. At most of the events, the "speaker" being paid by Insys did not speak, and, on many occasions, the only attendees at the events were the speaker and an Insys sales representative.

431. In December of 2016, six Insys executives and managers were indicted and then, in October 2017, Insys's founder and owner was arrested and charged with multiple felonies in connection with an alleged conspiracy to bribe practitioners to prescribe Subsys and defraud insurance companies. A U.S. Department of Justice press release explained that, among other things: "Insys executives improperly influenced health care providers to prescribe a powerful opioid for patients who did not need it, and without complying with FDA requirements, thus putting patients at risk and contributing to the current opioid crisis."[201] A Drug Enforcement Administration ("DEA") Special Agent in Charge further explained that: "Pharmaceutical companies whose products include controlled medications that can lead to addiction and overdose have a special obligation to operate in a trustworthy, transparent manner, because their customers' health and safety and, indeed, very lives depend on it."[202]

432. The tragic death of 32-year old Sarah Fuller in New Jersey illustrates that point well.

433. In exposing evidence of opioid manufacturers' "systemic" efforts to manipulate and deceive PBMs, [203] Senator Claire McCaskill released the audiorecording of an Insys employee lying about Ms. Fuller's diagnosis to a PBM employee so that the PBM would approve Subsys for her. [204] Ms. Fuller died of a Subsys-related overdoes the following year. The chilling recording can be heard here: https://www.hsgac.senate.gov/download/insys-call-full-audio.

434. As discussed above, the U.S. Department of Justice's investigation resulted in a

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[201] Press Release, U.S. Dep't of Just., U.S. Attorney's Office, Dist. of Mass., Founder and Owner of Pharmaceutical Company Insys Arrested and Charged with Racketeering (Oct. 26, 2017), https://www.justice.gov/usao-ma/pr/founder-and-owner-pharmaceutical-company-insys-arrested- and-charged-racketeering.
[202] *Id*.
[203] *See* https://www.beckershospitalreview.com/opioids/sen-mccaskill-releases-audio-recording-of-insys-employee-persuading-pbm-to-approve-off-label-fentanyl-use.html.
[204] *See* https://www.mccaskill.senate.gov/media-center/latest-headlines/sen-claire-mccaskill-finds-insys-inappropriately-pushed-opioid-to-patients.

$225 million settlement as well as the criminal conviction of its founder and other executives.

VII. The Marketing Conspirators' Widely Disseminated Misrepresentations and Omissions Were Deceptive and Created a Likelihood of Confusion or Misunderstanding as to the Safety and Efficacy of Opioids for Long-Term Use

435. The Marketing Conspirators' marketing of opioids for long-term use to treat chronic pain, both directly and through third parties, included information that was false, misleading, contrary to credible scientific evidence, and lacked balance and substantiation.

436. These misrepresentations and omissions were part of an organized campaign intended to penetrate the market for pain medication and convince prescribers, third-party payors. PBMs, and the public that opioids can and should be used to treat chronic pain. To this end, the Marketing Conspirators' marketing materials omitted material information about the risks of opioids, and overstated their benefits. They also inaccurately suggested that long-term opioid therapy was supported by evidence, and consistently failed to disclose the lack of evidence in support of treating long-term pain with opioids.

437. These misrepresentations and omissions were specifically directed at a broad target audience that included both consumers and providers such as physicians and pharmacists, as well as PBM and other insurers and reimbursement professionals.

438. There are seven primary categories of ***misleading, false, and unfounded*** representations that Marketing Conspirators engaged in individually, and in conjunction with purportedly independent third parties. Specifically, the Marketing Conspirators:

a. misrepresented the degree to which opioids improve patients' function and quality of life;

b. downplayed the link between long-term use of opioids and addiction;

c. misrepresented that addiction risk can be effectively managed;

d. masked the signs of addiction by promoting the misleading concept of "pseudoaddiction";

e. falsely claimed that opioid withdrawal symptoms can be easily addressed;

f. misrepresented that increasing doses of opioid poses no significant additional risks of abuse of addiction; and

g. overstated the risks and understated the efficacy of non-opioid based alternative pain treatments.

439. Exacerbating each of these misrepresentations was the collective effort of the Marketing Conspirators and their third party agents and allies to hide from the medical community material facts, including, for example, that there actually was – and is – an absence of "adequate and well-controlled studies of opioid use longer than 12 weeks."[205]

440. All of these misrepresentations and omissions, summarized above and described in further detail below, were deceptive to both ordinary consumers and the other members of the Marketing Conspirators' target audience, including doctors, insurers, third-party payors. PBMs and other health plan administrators. The overall impression arising from the totality of what Marketing Conspirators said – as well as what their statements and omissions reasonably implied – created a likelihood of misunderstanding, uncertainly, and confusion regarding the safe, recommended, and medically sound therapeutic uses of opioids to treat chronic pain.

441. The Marketing Conspirators' statements and omissions were not only likely to, but did in fact deceive and mislead consumers, insurers, PBMs and other health plan administrators and others into believing that opioids, when used to treat chronic pain, would be beneficial to patients' health, functioning, and quality of life, and would not lead to abuse or addiction, even at increasing doses. The Marketing Conspirators' target audience was further deceived and misled into believing that alternative, non-opioid pain treatments were inferior,

[205] Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013) (hereinafter "Woodcock Ltr., Sept. 10, 2013") *available at* http://docplayer.net/36264645-The-petition-requests-pertain-to-analgesia-products-therefore-this-response-is-limited-to-opioids-with-indications-for-analgesia.html.

ineffective, and unsafe.

442. The Marketing Conspirators disseminated their misrepresentation directly, and indirectly through Third Party Allies including KOLs and Front Groups. In disseminating these misrepresentations to the Marketing Conspirators' benefit, these Third Party Allies, while purporting to be independent patient-advocacy and professional organizations, in fact acted at Marketing Conspirators' behest and direction as the Marketing Conspirators' agents or servants within the course and scope of their agency or service. The Marketing Conspirators accordingly are responsible for the conduct of their Third Party Allies as alleged herein.

A. In Their Deceptive Marketing, the Marketing Conspirators and their Third Party Allies Misrepresented that Prescription Opioids Improve Patients' Ability to Function and Improve their Quality of Life

443. Each of the Marketing Conspirators' documents and other materials outlined below was created to promote opioids sales and use so that doctors would prescribe them, patients would actively seek them, and insurers and health plan administrators would approve the drugs for inclusion in – and payment of reimbursement from – private and public health plans. These materials also encouraged doctors and others to continue or approve continuation of opioid therapy in the belief that failure to improve pain, function, or quality of life with initial doses of opioids could be overcome by increasing doses or prescribing additional short-acting opioids on an as-needed basis for breakthrough pain.

444. In addition and as set forth above, the Marketing Conspirators ignored, however, not only that there was no evidence that opioids improved long-term functioning, but also a 2006 study found that "[f]or function outcomes … other [non-opioid] analgesics were significantly more effective than were opioids."[206]

[206] Andrea D. Furlan et al., *Opioids for Chronic Noncancer Pain: A Meta-Analysis of Effectiveness and Side Effects,*

445. As set forth previously, studies of the use of opioids for chronic conditions for which they are commonly prescribed, such as low back pain, corroborate this conclusion and have failed to demonstrate an improvement in patients' function. For example, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not lead patients to return to work or physical activity.[207] Moreover, users of opioids had the highest increase in the number of headache days per month, scored significantly worse on the Migraine Disability Assessment (MIDAS), and had higher rates of depression, compared to non-opioid users.[208]

446. As set forth previously, long-term use of opioids exposes users to a host of known, serious risks, including risks of misuse, abuse, addiction, overdose, and death. Chronic opioid therapy can also cause side effects including mental clouding and confusion, sleepiness, hyperalgesia, constipation, and immune-system and hormonal problems that degrade, rather than improve, patients' ability to function. Marketing Conspirators omitted these adverse effects, as well as certain risk of drug interaction, from their publications and marketing efforts.

447. Each of the following specific statements by the Marketing Conspirators in their deceptive marketing of opioids misrepresent the degree, if any, to which the long-term use of opioids actually improves patients' function and quality of life, and falsely suggest that scientific evidence supports the long-term use of opioids to improve patients' function and quality of life.

174(11) Can. Med. Ass'n J. 1589-1594 (2006), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1459894/. This study revealed that efficacy studies do not typically include data in opioid addiction, such that, if anything, the data overstate effectiveness.

[207] BA Martell *et al.*, *Systematic Review: Opioid Treatment for Chronic Back Pain: Prevalance, Efficacy, and Association with Addiction*, Annals of Internal Medicine (2007), *available at* https://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0024176/; Richard Deyo *et al.*, *Opioids for Low Back Pain*, BMJ Publishing (Jan. 5, 2015), *available at* http://www.bmj.com/content/350/bmj.g6380.

[208] *Survey: Migraine Patients Taking Potentially Addictive Barbiturate or Opioid Medications Not Approved by FDA as Migraine Treatments* (May 15, 2017), *available at* https://www.thefreelibrary.com/Survey%3A+Migraine+Patients+Potentially+Addictive+Barbiturate+or+…-a0163389345.

448. These statements, which were directly contrary to the true facts, created a likelihood of confusion or misunderstanding as to the purported benefits of chronic opioid therapy, and in particular the ability of opioids to improve both patients' ability to function and quality of life. These statements were also likely to, and did, make a difference in the purchasing, prescribing, and reimbursing decisions of doctors, patients, and others, since they were designed to convince members of the Marketing Conspirators' target audience that opioids were safe and effective, and to choose opioids over alternative treatment therapies for chronic pain:

1. Actavis

a. On information and belief, Actavis trained its sales force to instruct prescribers that "most chronic benign pain patients do have markedly improved ability to function when maintained on chronic opioid therapy" and that increasing and restoring function is an expected outcome of long-term Kadian therapy, including physical, social, vocational, and recreational function.

b. Actavis distributed a product brochure and detailing document that claimed that use of Kadian to treat chronic pain would relieve "stress on your body and your mental health," allow patients to avoid "miss[ing] work," and cause patients to better enjoy their lives. Government regulators warned Actavis that such claims were misleading, writing: "We are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug has in alleviating pain, taken together with any drug-related side effects patients may experience ... results in an overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life." The regulators concluded that the representations were "false or misleading

because they omit and minimize the serious risks associated with the drug... and present unsubstantiated superiority and effectiveness claims.... These violations are a concern from a public health perspective because they suggest that the product is safer and more effective than has been demonstrated."

2. Cephalon

a. Cephalon sponsored the FSMB's Responsible Opioid Prescribing (2007), which taught that relief of pain itself improved patients' function. Responsible Opioid Prescribing explicitly describes functional improvement as the goal of a "long term therapeutic treatment course." Cephalon spent $150,000 to purchase copies of this book in bulk and distribute in through its pain sales force to 10,000 prescribers and 5,000 pharmacists.

b. Cephalon sponsored the American Pain Foundation's Treatment Options: A Guide for People Living with Pain (2007), which taught patients that opioids when used properly "given [pain patients] a quality of life we deserve." The Treatment Options guide notes that non-steroidal anti-inflammatory drugs have greater risks associated with prolonged duration of use, but there was no similar warning for opioids. APF distributed 17,200 copies in one year alone, according to its 2007 annual report. The publication is currently available online.

c. Cephalon sponsored a CME written by KOL Dr. Webster, titled Optimizing Opioid Treatment for Breakthrough Pain, which was offered online by Medscape, LLC from September 28, 2007 to December 15, 2008. The CME taught that Cephalon's Actiq and Fentora improve patients' quality of life and allow for more activities when taken in conjunction with long-acting opioids.

d. Cephalon's 2006 marketing plan for marketing of Fentora, which was reviewed and approved at the highest levels of the company's management, was aimed at various types of pain management, including for "chronic pain patients," among other things. The marketing focus was to "generate awareness, understanding, and appropriate use of [Fentora] for breakthrough pain." A "target patient" was the patient "suffering from chronic pain."

e. On information and belief, Cephalon sales representatives misled prescribers as to the degree that opioids would increase patients' ability to function and improve their quality of life.

3. Endo

a. Endo sponsored a website, painknowledge.com, through APF and NIPC, which in 2009 claimed that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it.

b. A CME sponsored by Endo, titled Persistent Pain in the Older Patient, taught that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."

c. Endo distributed handouts to prescribers that claimed that use of Opana ER to treat chronic pain would allow patients to perform work, for example as a chef. The flyer also emphasized Opana ER's indication without including equally prominent disclosure of the "moderate to severe pain"

qualification.

d. Endo's sales force distributed FSMB's Responsible Opioid Prescribing (2007), which taught that relief of pain itself improved patients' function. Responsible Opioid Prescribing explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course."

e. Endo provided grants to APF to distribute the book *Exit Wounds* in order to convince returning veterans and their families that opioids were an effective way to "increase [veterans'] level of functioning. Notably, although benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder, the book omits warnings of the risk of fatality when mixing opioids and benzodiazepines.

f. On information and belief, Endo sales representatives misled prescribers as to the degree that opioids would increase patients' ability to function and improve their quality of life.

4. Insys

a. Insys sales representatives misled prescribers and patients alike as to the degree that opioids would increase patients' ability to function and improve their quality of life.

b. The dangers inherent in these deceptions are exemplified by the tragic death of Sarah Fuller, who had been prescribed Subsys by a physician. Ms. Fuller's physician had been misled by an Insys sales representative into believing that Subsys was appropriate for treating chronic non-cancer pain. Ms. Fuller herself was also misled about the safety and efficacy of Subsys by an Insys sales

representative who met directly with Ms. Fuller in order to "teach" her about Subsys. Ms. Fuller died the following year of a Subsys-related overdose at the age of 32.

5. Janssen

a. Janssen sponsored a patient education guide titled Finding Relief: Pain Management for Older Adults (2009), which its personnel reviewed and approved, and its sales force distributed. This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, walking, and climbing stairs. The guide states as a "fact" that "opioids may make it easier for people to live normally." The myth/fact structure implies authoritative backing for the claims, which does not exist. The targeting of older adults also ignored heightened opioid risk in this population.

b. Janssen sponsored, developed, and approved content of the website Let's Talk Pain in 2009, acting in conjunction with the APF, AAPM, and the American Society of Pain Management Nursing ("ASPMN"), whose participation in Let's Talk Pain was financed and orchestrated by Janssen. This website featured an interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," inaccurately implying that her experience would be representative of what other patients can expect to experience.

c. Janssen provided grants to APF to distribute to veterans the book *Exit Wounds*, which taught that opioid medications "increase your level of

functioning." *Exit Wounds* also omitted warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk.

d. On information and belief, Janssen sales representatives misled prescribers as to the degree that opioids would increase patients' ability to function and improve their quality of life.

6. Mallinckrodt

a. Mallinckrodt sponsored the FSMB's Responsible Opioid Prescribing (2007), which taught that relief of pain itself improved patients' function. Responsible Opioid Prescribing explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." Mallinckrodt spent at least $100,000 to support distribution of the book to state medical boards.

b. On information and belief, Mallinckrodt misled prescribers as to the degree that opioids would increase patients' ability to function and improve their quality of life.

7. Purdue

a. Purdue's unbranded website In the Face of Pain (inthefaceofpain.com) contained testimonials from various "Advocates" who commented about opioids. One such advocate, Dr. Portenoy, advocated the use of opioids because, in his words: "The negative impact of unrelieved pain on the lives of individuals … is no longer a matter of debate. The unmet needs of millions of patients combine into a major public health concern." This statement was available on inthefaceofpain.com through at least 2014 and 2015. The NYAG

reached a settlement agreement with Purdue in 2015 regarding the misleading nature of these representations. See discussion *infra*.

b. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals titled "Pain Vignettes." They were case studies featuring patients, each with pain conditions persisting over several months, recommending OxyContin for each. One such patient, Paul, is described as a "54-year-old writer with osteoarthritis of the hand," and the vignettes imply that an OxyContin prescription will help him work more effectively.

c. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management (2011), which inaccurately claimed that "multiple clinical studies" had shown that opioids are effective in "improving daily function, psychological health, and health-related quality of life for chronic pain patients."

d. Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which counseled patients that opioids, when used properly, "give [pain patients] a quality of life we deserve." APF distributed 17,200 copies in one year alone, according to its 2007 annual report.

e. Purdue sponsored APF's book *Exit Wounds* (2009), which taught veterans and their families that opioids were an effective way to "increase [veterans'] level of functioning. Notably, although benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder, the book omitted warnings of the risk of fatality when mixing opioids and benzodiazepines.

f. Purdue sponsored the FSMB's Responsible Opioid Prescribing (2007), which taught that relief of pain itself improved patients' function.

Responsible Opioid Prescribing explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." Purdue also spent over $100,000 to support distribution of the book.

g. On information and belief, Purdue sales representatives misled prescribers as to the degree that opioids would increase patients' ability to function and improve their quality of life.

B. In Their Deceptive Marketing, the Marketing Conspirators and Their Third Party Allies Failed to Properly Disclose the Truth about the Risk of Addiction from Long-Term Opioid Use

449. The dangerous and deceptive failure to disclose the risks that opioids are highly addictive is central to the Marketing Conspirators' marketing.

450. To reach chronic pain patients, the Marketing Conspirators and their Third Party Allies had to overcome doctors' legitimate fears that patients would become addicted. The risk of addiction is an extremely weighty risk, condemning patients to a disease that is chronic, progressive, and if not properly treated – often fatal. In addition, addiction recovery carries a lifetime risk of relapse.

451. Absent Marketing Conspirators' campaigns to convince doctors otherwise, it would be highly unlikely for a reasonable physician to find that the benefits from long-term opioid use for many aspects of chronic pain sufficiently outweighed the risk of addiction to justify writing the prescription.

452. Through their well-funded, widespread, and comprehensive marketing efforts, the Marketing Conspirators and their KOLs and Front Groups were able to change the prescribing behavior of their peers despite the well-settled historical understanding and clear evidence that opioids taken long-term are very often addictive.

453. The Marketing Conspirators and their Third Party Allies: (i) maintained that the risk of addiction for patients who take opioids long-term was low; and (ii) failed to properly disclose the addiction risk as an adverse effect, even though the frequency and magnitude of the risk compelled disclosure.

454. The Marketing Conspirators also used code words that conveyed to prescribers and patients that their product was less prone to abuse and addiction than competitor products. For example, sales representatives for Marketing Conspirators Actavis, Endo, Janssen, and Purdue promoted their drugs as having "steady-state" properties, implying that their drugs caused less of a rush or a feeling of euphoria, which can trigger abuse and addiction.

455. Further, Endo actively promoted its reformulated Opana ER on the basis that it was "designed to be crush-resistant," suggesting that Endo had succeeded in making the drug harder to adulterate and abuse.[209] In fact, however, the clinical significance of Endo's crush resistant formulation or its impact on abuse and misuse has not been established for Opana ER, and Opana ER could still be ground and cut into small pieces by those looking to abuse the drug and could still be taken in unwarranted dosages or diverted to unauthorized users.

456. Similarly, Purdue falsely suggested that OxyContin's design made it less likely to be abused.

457. Each of the statements alleged herein was created by the Marketing Conspirators with the expectation that, by instructing prescribers and patients that addiction rates are low, doctors would prescribe opioids to more patients. For example, one publication sponsored exclusively by Purdue – APF's *A Policymaker's Guide to Understanding Pain & Its*

[209] https://www.prnewswire.com/news-releases/endo-announces-fda-approval-of-a-new-formulation-of-opana-er-designed-to-be-crush-resistant-135431073.html.

Management (2011) – claimed that opioids are not prescribed often enough because of "misconceptions about opioid addiction."[210]

458. Acting directly or with and through third parties, each Marketing Conspirator falsely claimed that the potential for addiction from opioids was relatively small, or non-existent, even though there was no scientific evidence to support those claims, and the available research contradicted them. For example, a 2015 literature survey found that rates of "misuse" averaged between 21% and 29%, and rates of "addiction" ranged between 8% and 12%.[211] These estimates are well in line with Purdue's own undisclosed studies, showing that between 8% and 13% of OxyContin patients became addicted,[212] but on which Purdue chose not to rely, instead citing the Porter-Jick letter as evidence of non-addiction.

459. Government regulators have noted that 26% of opioid patients obtain opioids from two or more prescribers, 16.5% get early refills, and 20% use two or more pharmacies – all potential "red flags" for abuse or addiction.[213] Regulators in fact have ordered manufacturers of long-acting opioids to "[c]onduct one or more studies to provide quantitative estimates of the serious risks of misuse, abuse, addiction, overdose and death associated with long-term use of opioid analgesics for management of chronic pain," in recognition of the fact that they found

[210] https://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.
[211] Kevin Vowles *et al.*, *Rates of Opioid Misuse, Abuse, and Addiction in Chronic Pain: a Systematic Review and Data Synthesis*, 156 PAIN 56**9-7**6 (April 2015), *available at* https://www.researchgate.net/publication/271445179_Rates_of_opioid_misuse_abuse_and_addiction_inchronic_pai
[212] Lawrence Robbins, *Long-Acting Opioids for Severe Chronic Daily Headache*, 10(2) Headache Quarterly 135 (1999); Lawrence Robbins, *Works in Progress: Oxycodone CR, a Long-Acting Opioid, for Severe Chronic Daily Headache*, 19 Headache Quarterly 305 (1999).
[213] Len Paulozzi, M.D., *Abuse of Marketed Analgesics and Its Contribution to the National Problem of Drug Abuse*, *available at* https://wayback,archive-it.org/7993/20170405203727/ https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM233244.pdf.

"high rates of addiction" in the medical literature.[214]

460. The significant and growing incidence of abuse, misuse, and addiction to opioids are also powerful evidence that Marketing Conspirators' statements regarding the low risk of addiction were, and are, untrue. This was well-known to and ignored by the Marketing Conspirators who had access to sales data and reports, adverse event reports, federal abuse and addiction-related surveillance data, and other sources that demonstrated the widening epidemic of opioid abuse and addiction.

461. Acting directly or through and with third parties, the Marketing Conspirators claimed in their deceptive marketing that the potential for addiction from long-term use of opioids was relatively small or non-existent, despite the fact that the contention was false and there was no scientific evidence to support it. The Marketing Conspirators' efforts to trivialize and conceal the potential for abuse and addiction posed by opioids created a likelihood of confusion or misunderstanding as to the safety of opioids, and falsely suggested that patients need not worry about addiction risks when using opioids for chronic pain management.

462. A non-exhaustive list of examples of the Marketing Conspirators' misrepresentations in this regard is set forth below:

1. Actavis

a. Documents from a 2010 sales training indicate that Actavis trained its sales force that long-acting opioids were less likely to produce addiction than short-acting opioids, although there is no evidence that either form of opioid is less addictive or that any opioids can be taken long-term without the risk of

[214] September 10, 2013 letter from Bob Rappaport, M.D., to NDA applicants of ER/LA opioid analgesics, *available at* http//www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM367697.pdf; Woodcock Ltr., Sept. 10, 2013, *supra* note 205.

addiction.

b. Actavis had a patient education brochure distributed in 2007 that claimed addiction is "less likely if you have never had and addiction problem." The overall presentation suggests the risk is so low as not to be a concern.

c. Kadian sales representative told prescribers that Kadian was "steady state" and had extended-release mechanisms, the implication of which was that it did not produce a rush or euphoric effect, and therefore was less addictive and less likely to be abused.

d. Kadian sales representatives told prescribers that the contents of Kadian could not be dissolved in water if the capsule was opened, implying that Kadian was less likely to be abused, and thereby less addictive, than other opioids.

e. On information and belief, Actavis sales representatives omitted any discussion of addiction risks when discussing Actavis opioid products, including Kadian, with prescribers. In a July 2010 "Dear Doctor" letter mandated by government regulators required Actavis to acknowledge to the doctors to whom it marketed its opioid drugs that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed … promotional materials that … omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."

2. Cephalon

a. Cephalon sponsored and facilitated the development of a guidebook titled Opioid Medications and REMS: A Patient's Guide, which claims that "patients with a history of abuse or a family history of abuse do not commonly become addicted to opioids."

b. Cephalon sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

c. On information and belief, Cephalon sales representatives omitted any discussion of addiction risks when discussing Cephalon's opioid products with prescribers.

3. Endo

a. On Endo's website www.opana.com, Endo claimed until at least April 2012 that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted." The New York Attorney General investigated this statement, found that Endo had no evidence for the statement, and reached a settlement with Endo requiring corrective action. *See* discussion *infra*.

b. Similarly, Endo also provided training materials to its sales representatives stating that addiction to opioids is not common, and that "symptoms of withdrawal do not indicate addiction." The NYAG found that those statements were unwarranted. *See* discussion *infra*.

c. Endo's advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant, conveying that it was less likely to be abused. This claim was false. Government regulators warned in a May 10, 2013 letter that there was no evidence that Endo's design would "provide a reduction in oral, intranasal or intravenous abuse," and that Endo's "post-marketing data submitted are insufficient to support any conclusion about the overall or route-specific rates of abuse."

d. Endo sponsored a website, painknowledge.com, through APF and NIPC, which in 2009 claimed that "[p]eople who take opioids as prescribed usually do not become addicted." The overall presentation suggests that the risk is so low as not to be a concern. The language also implies that, as long as a prescription is given, opioid use will not become problematic. Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it.

e. Endo sponsored a website, PainAction.com, which stated: "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

f. Endo sponsored CMEs published by APF's NIPC, of which Endo was the sole funder, titled Persistent Pain in the Older Adult and Persistent Pain in the Older Patient. These CMEs claimed that opioids used by elderly patients present "possibly less potential for abuse than in younger patients," which lacks evidentiary support and deceptively minimizes the risk of addiction for elderly patients.

g. Endo distributed an education pamphlet with the Endo logo titled Living with Someone with Chronic Pain, which inaccurately minimized the risk of addiction, stating: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem."

h. Endo distributed a patient education pamphlet edited by KOL Dr. Portenoy titled Understanding Your Pain: Taking Oral Opioid Analgesics (2004). It claimed that "[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems." This implies that pain patients prescribed opioids will not become addicted, which is unsupported and untrue. It is still available online.

i. Endo contracted with the American Geriatrics Society ("AGS") to produce a CME promoting the 2009 Guidelines, titled Pharmacological Management of Persistent Pain in Older Persons (2009). The guidelines falsely claim that the "risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." None of the references in the guidelines corroborates the claim that elderly patients are less likely to become addicted to opioids, and there is no such evidence. Endo was aware of the AGS guidelines' content when it agreed to provide its funding, and AGS drafted the guidelines with expectation that it would seek drug company funding to promote them after their completion.

j. Endo sales representative told prescribers that its drugs were "steady state," implying that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused.

k. Endo provided grants to APF to distribute the book *Exit Wounds* (2009) to veterans, which taught that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." The overall presentation suggests that the risk is so low as not to be a concern.

l. On information and belief, Endo sales representatives omitted discussion of addiction risks related to Endo's opioid drugs when discussing Endo's opioid products with prescribers.

4. Insys

a. Insys sales representatives misled prescribers and patients alike in discussions about the risks and permissible uses of Subsys.

b. Insys also created and disseminated to prescribers across the nation increasingly deceptive template letters of medical necessity ("LMN") in order to secure insurance reimbursement for off-label Subsys prescriptions. For example, in 2013, Insys created and disseminated "the strong LMN," which represented that "[t]he literature since 2007 shows a favorable safety profile [for Rapid Onset Opioids]," but omitted any reference to the risk of addiction (or a host of other dangers attendant to using an opioid such as Subsys, including induced, hyperalgesia respiratory depression and death).

5. Janssen

a. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and which its sales force distributed. This guide described a "myth" that

opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain." The overall presentation suggests that the risk is so low as not to be a concern. The language also implies that as long as a prescription is given, opioid use is not a problem.

b. Janssen contracted with AGS to produce a CME promoting the 2009 Guidelines, titled Pharmacological Management of Persistent Pain in Older Persons. The Guidelines falsely claim that the "risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." The study supporting this assertion does not analyze addiction rates by age. As previously noted, addiction remains a significant risk for elderly patients. Janssen was aware of the AGS guidelines' content when it agreed to provide its funding, and AGS drafted the guidelines with the expectation that it would seek drug-company funding to promote them after their completion.

c. Janssen provided grants to APF to distribute the book *Exit Wounds* (2009) to veterans, which taught that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." The overall presentation suggests that the risk is so low as not to be a worry.

d. Janssen ran a website, Prescriberesponsibly.com, which claimed that concerns about opioid addiction are "overstated."

e. A June 2009 Nucynta training module warned Janssen's sales force that physicians are reluctant to prescribe controlled substances like Nucynta,

but this reluctance is unfounded because "the risks … are much smaller than commonly believed."

f. Janssen sales representatives told prescribers that its drugs were "steady state," implying that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused.

g. Janssen sales representatives told prescribers that Nucynta and Nucynta ER were "not opioids," implying that the risks of addiction and other adverse outcomes associated with opioids were not applicable to these drugs. In truth, however, as set out in Nucynta's product label, Nucynta "contains tapentadol, an opioid agonist and Schedule II substance with abuse liability similar to other agonists, legal or illicit.

h. Janssen's sales representative told prescribers that Nucynta's unique properties eliminated the risk of addiction associated with the drug.

i. On information and belief, Jansen sales representatives omitted discussion of addiction risks related to Janssen's opioid drugs when discussing Janssen's products with prescribers.

6. Purdue

a. A 2017 study funded by Purdue to analyze medical costs associated with opioid addiction noted: "[N]early 100 million American live with chronic pain .... For moderate to severe pain, opioids can provide significant symptom relief." The study made no reference to the distinction in addiction risks between short-term and long-term use.

b. Purdue published a prescriber and law enforcement education

pamphlet titled Providing Relief, Preventing Abuse (2011), which under the heading "Indication of Possible Drug Abuse," shows pictures of the stigmata of injecting or snorting opioids – skin popping, track marks, and perforated nasal septa. In fact, opioid user who resort to these extremes are uncommon; the far more typical reality is patients who become dependent and addicted through oral use. Thus, these representations deceptively reassured doctors that, as long as they do not observe those sign of misuse, they need not be concerned that patients are abusing or addicted to opioids.

c. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management (2011), which inaccurately claimed that less than 1% of children prescribed opioids will become addicted. The publication also asserted that pain is "undertreated" due to "misconceptions about opioid addiction."

d. Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which asserted that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

e. A Purdue-funded study with a Purdue co-author claimed that "evidence of the risk of psychological dependence or addiction is low in the absence of a history of substance abuse." The study relied only on the Porter-Jick letter to the editor concerning a review of charts of hospitalized patients, not patients taking Purdue's long-acting, take-home opioid. The overall presentation suggests that the risk is so low as not to be of concern.

f. Purdue contracted with AGS to produce a CME promoting the

2009 Guidelines titled Pharmacological Management of Persistent Pain in Older Persons. The guidelines falsely claim that the "risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." None of the references in the guidelines corroborate the claim that elderly patients are less likely to become addicted to opioids and the claim is, in fact, untrue. Purdue was aware of the AGS guidelines' content when it agreed to provide its funding, and AGS drafted the guidelines with the expectation that it would seek drug company funding to promote them after their completion.

g. Purdue sponsored APF's book *Exit Wounds* (2009), which counseled veterans that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." The overall presentation suggests that the risk is so low as not to be a concern.

h. Purdue sales representatives told prescribers that its drugs were "steady state," implying that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused.

i. Purdue sales representatives told prescribers that Butrans has a lower abuse potential than other drugs because it was essentially tamper-proof and, after a certain point, patients no longer experience a "buzz" from increased dosage.

j. Advertisements that Purdue sent to prescribers stated that OxyContin FR was less likely to be favored by drug addicts, and therefore, less likely to be abused or diverted, or result in addiction.

k. Purdue sales representatives emphasized that Purdue's ER/LA opioids (OxyContin, Butrans, and Hysingla) provide slow-onset, stable doses without "peaks and valleys" – encouraging prescribers to infer that these opioids are safer because they do not produce the euphoric high that fosters addiction. In a 2011 sales training document, Purdue acknowledged that the "fewer peaks and valleys" message seen in a review of sales representative call notes was "problematic" – confirming both that the statements were made and that they were false.

l. On information and belief, Purdue sales representatives omitted discussion of addiction risks related to Purdue's opioid drugs when discussing Purdue's opioid products with prescribers.

463. Rather than honestly disclose the risks of opioid abuse and addiction in their marketing materials, the Marketing Conspirators and their Third Party Allies falsely and improperly portrayed those who were concerned about addiction as unfairly denying treatment to needy patients. For example, to increase pressure on doctors to prescribe long-term opioid therapy, the Marketing Conspirators deceptively suggested that doctors who did not treat their patients' chronic pain with opioids were failing their patients, and would potentially be subject to discipline.

464. The Marketing Conspirators and their Third Party Allies also claimed that overblown worries about addiction cause pain to be *under-treated* and cause opioids to be *under-prescribed* and over-regulated. This reinforced the Marketing Conspirators' marketing messages that the risks of addiction and abuse were exaggerated and not significant.

465. For example, Janssen's website *Let's Talk Pain* warned in a video posted online

that: "[S]trict regulatory control has made many physicians reluctant to prescribe opioids. The unfortunate casualty in all of this is the patient, who is often undertreated and forced to suffer in silence." The program continued on to say: "Because of the potential for abusive and/or addictive behavior, many healthcare professionals have been reluctant to prescribe opioids for their patients .... This prescribing environment is one of many barriers that may contribute to the undertreatment of pain, a serious problem in the United States."

466. Similarly, Purdue's website *In the Face of Pain*, under the heading "Protecting Access," complains that, through mid-2013, policy governing the prescribing of opioids was "at odds" with best medical practices by: (i) "unduly restricting the amounts that can be prescribed and dispensed;" (ii) "restricting access to patients with pain who also have a history of substance abuse;" and (iii) "requiring special government-issued prescription forms only for the medications that are capable of relieving pain that is severe." This unsupported and untrue rhetoric aims to portray doctors who do not prescribe opioids as ignoring industry best practices, converting their desire to relieve patients' suffering into a mandate to prescribe opioids.

C. In Their Deceptive Marketing, the Marketing Conspirators and Their Third Party Allies Misrepresented that Opioid Addiction Risk Can Be Avoided or Managed

467. Several Marketing Conspirators continue to maintain that most patients can safely take opioids long-term for chronic pain without becoming addicted. Presumably to explain why doctors encounter so many patients addicted to opioids, the Marketing Conspirators and their Third Party Allies have come to admit that some patients could become addicted, but that doctors can avoid or manage that risk by using screening tools or questionnaires. These tools, they say, purport to identify those with allegedly higher addiction risks (stemming, for example, from personal or family histories of substance abuse or mental illness) so that doctors can more

closely monitor patients at greater risk of addiction.

468. The Marketing Conspirators' assertions that doctors can readily identify and manage addiction risk are not true. There is no reliable scientific evidence that screening works to accurately predict risk or reduce rates of addiction, and there is no scientific evidence that screening or any other precautions can remove the risk of addiction.

469. Despite the use of screening tools, patients with past substance use disorders – which every tool rates as a risk factor – receive, on average, higher doses of opioids from their physicians.

470. In addition to making deceptive representations about screening, Marketing Conspirator Purdue has deceptively marketed its so-called "abuse-deterrent" opioids – a reformulated version of OxyContin and Hysingla ER – in a manner that falsely implied these drugs can curb abuse and even addiction. In this marketing, which began in 2010, Purdue focused not on oral abuse, which is the most common form of prescription opioid abuse, but instead claimed that abuse and addiction result from product diversion, with abusers snorting or injecting the drug. Purdue misleadingly assured prescribers and other members of its target audience that its new formulation, which made its opioids more difficult to crush or inject, would prevent or reduce misuse, abuse, or diversion.

471. Specifically, Purdue and its sales representatives have falsely claimed or implied that Purdue's abuse-deterrent formulations: (i) prevent tampering and cannot be crushed or snorted; (ii) prevent or reduce opioid abuse, diversion, and addiction overall; and (iii) are safer than other opioids. At the same time, Purdue either failed to disclose that the abuse-deterrent formulations do not impact the most common forms of abuse – oral ingestion – or affirmatively misrepresented that most abuse is by non-oral means.

472. In fact, there is no substantial scientific evidence that Purdue's abuse-deterrent opioids actually reduce opioid abuse. As the 2016 CDC Guideline states, "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," and the technologies – even when they work – "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."[215]

473. Purdue's deceptive marketing of the benefits of its abuse-deterrent formulations is particularly dangerous because it persuades doctors, who might otherwise curtail their opioid prescribing, to continue prescribing Purdue's opioids in the mistaken belief that they are safer. It also allows prescribers, patients, and other members of Purdue's target audience to discount evidence of opioid addiction and attribute it to other, less safe opioids — *i.e.*, to believe that while patients might abuse or overdose on non-abuse deterrent opioids, Purdue's opioids did not carry that risk.

474. A 2014 *Evidence Report* by the Agency for Healthcare Research and Quality ("AHRQ"), which "systematically review[ed] the current evidence on long-term opioid therapy for chronic pain," identified "[n]o study" that had "evaluated the effectiveness of risk mitigation strategies, such as use of risk assessment instruments, opioid management plans, patient education, urine drug screening, prescription drug monitoring program data, monitoring instruments, more frequent monitoring intervals, pill counts, or abuse-deterrent formulations on outcomes related to overdose, addiction, abuse or misuse."[216]

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[215] *CDC Guideline*, March 18, 2016 at pg. 22, *supra* note 8; *see also* Theodore J. Cicero & Matthew J. Ellis, *Abuse-Deterrent Formulations and the Prescription Opioid Abuse Epidemic in the United States: Lessons Learned from OxyContin*, 72(5) JAMA Psychiatry 424-430 (May 2015).

[216] *The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain*, Agency for Healthcare Research and Quality (Sept. 19, 2014), *available at* https://ahrq-ehc-application.s3.amazonaws.com/media/pdf/chronic-pain-opioid-treatment_research.pdf.

475. The Marketing Conspirators' representations that the risk of addiction could be readily avoided or managed, and Purdue's representations that its abuse-deterrent formulations could help thwart addiction and abuse, are deceptive and without scientific support, as described below. These misrepresentations by the Marketing Conspirators, which were intended to persuade prescribers, patients, and health care payors to choose opioids over competing medications and therapies, were likely to, and did, confuse, deceive, and mislead the Marketing Conspirators' target audience into believing that addiction, misuse, and abuse could easily be avoided or managed. The Marketing Conspirators' misrepresentations were not only likely to, but did in fact, make a difference in purchasing and prescribing decisions of patients, doctors, and other third-party payors, as they minimized the risks associated with opioids for chronic pain, and influenced the public to choose opioids over other pain relief therapies.

476. The misrepresentations included the following:

1. Actavis

a. Documents from a 2010 sales training indicate that Actavis trained its sales force to teach that prescribers can use risk screening tools to limit the development of addiction.

2. Cephalon

a. Cephalon sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which taught patients that "opioid agreements" between doctors and patients can "ensure that you take the opioid as prescribed." .

3. Endo

a. Endo paid for a 2007 supplement available for CME credit in the Journal of Family Practice. This publication, titled Pain Management Dilemmas

in Primary Care: Use of Opioids, recommended screening patients using tools like the Opioid Risk Tool or the Screener and Opioid Assessment for Patients with Pain, and advised that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

4. Purdue

a. Purdue's unbranded website In the Face of Pain (inthefaceofpain.com) stated that policies that "restrict[] access to patients with pain who also have a history of substance abuse" and "requiring special government-issued prescription forms for the only medications that are capable of relieving pain that is severe" are "at odds" with best medical practices. The NYAG reached a settlement agreement with Purdue in 2015 regarding the misleading nature of this website. The NYAG found that the website created a false impression of impartiality and concealed that Purdue made significant financial contributions to many paid speakers whose testimonials appeared on the website. *See* discussion *infra*.

b. Purdue sponsored a CME program taught by a KOL titled Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes (2012). This presentation recommended that use of screening tools, more frequent refills, and switching opioids could treat a high-risk patient showing signs of potentially addictive behavior.

c. Purdue sponsored a 2011 webinar taught by KOL Dr. Webster, titled Managing Patient's Opioid Use: Balancing the Need and Risk. This

publication taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths."

d. On information and belief, Purdue sales representatives told prescribers that screening tools can be used to select patients appropriate for opioid therapy and to manage the risks of addiction.

e. On information and belief, Purdue sales representatives told prescribers that Purdue's abuse-deterrent formulations of its oral opioids OxyContin and Hysingla are more difficult to abuse and less likely to be diverted.

D. In Their Deceptive Marketing, the Marketing Conspirators and Their Third Party Allies Created Confusion as to Opioid Addiction Risks by Promoting the Misleading Term "Pseudoaddiction"

477. The Marketing Conspirators and their Third Party Allies developed and disseminated each of the following misrepresentations about "pseudoaddiction" so that, by instructing patients and prescribers that signs of addiction are actually the result of under-treated pain, doctors would prescribe more opioids to more patients and continue prescribing them, and patients would continue to use opioids despite signs of addiction. The term "pseudoaddiction," wholly lacked scientific evidence but quickly became a common way for the Marketing Conspirators and their allies to promote the use of opioids even to patients displaying addiction symptoms.

478. The concept of "pseudoaddiction" was coined by Dr. Haddox, who went to work for Purdue, and popularized by KOL Dr. Portenoy, who consulted for Defendants Cephalon, Endo, Purdue, and Mallinckrodt. Much of the same language appears in other Marketing Conspirators' treatments of this issue, blurring the line between undertreated pain and true

addiction, as if patients could not experience both.

479. KOL Dr. Webster subsequently conceded that: "[Pseudoaddiction] obviously became too much of an excuse to give patients more medication.... It led us down a path that caused harm. It is already something we are debunking as a concept."[217] Notwithstanding this revealing, if incomplete admission, the Marketing Conspirators actually continued and even increased their marketing campaign to downplay the risks of addiction.

480. Each of the Marketing Conspirators' statements identified below falsely states or suggests that the concept of pseudoaddiction is substantiated by scientific evidence and accurately describes the condition of undertreated patients who need, and should be treated with, more opioids. These misrepresentations, which were intended to persuade prescribers, patients, and third-party payors to choose opioids over competing medications and therapies, were likely to, and did, confuse, deceive, and mislead the Marketing Conspirators' target audience about the true safety of opioids and risks of addiction. These misrepresentations were not only likely to, but did in fact, make a difference in the purchasing and prescribing decisions of patients, doctors, and other third-party payors, as the Marketing Conspirators' misleading marketing promoted the concept of "pseudoaddiction" and thereby downplayed the true risks of addiction and convinced the public to choose opioids over other pain relief therapies.

481. The misrepresentations included the following:

1. Actavis

a. Documents from a 2010 sales training indicate that Actavis trained its sales force to instruct physicians that aberrant behaviors like self-escalation of doses constituted "pseudoaddiction."

[217] John Fauber *et al.*, *Networking Fuels Painkiller Boom*, Milwaukee Wisc. J. Sentinel (Feb. 19, 2012), *available at* http://bangordailynews.com/2012/02/19/health/networking-fuels-painkiller-boom/.

2. Cephalon

a. Cephalon sponsored FSMB's Responsible Opioid Prescribing (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding opioids are all signs of "pseudoaddiction." Cephalon also spent $150,000 to purchase copies of the book in bulk and distributed it through its pain sales force to 10,000 prescribers and 5,000 pharmacists.

3. Endo

a. Endo distributed copies of a book by KOL Dr. Webster titled Avoiding Opioid Abuse While Managing Pain (2007). Endo's internal planning documents described the purpose of distributing this book as to "[i]ncrease the breadth and depth of the Opana ER prescriber base." The book claims that when faced with signs of aberrant behavior, the doctor should regard it as "pseudoaddiction" and that "increasing the dose in most cases … should be the clinician's first response."

b. Endo spent $246,620 to buy copies of FSMB's Responsible Opioid Prescribing (2007), which was distributed by Endo's sales force. This book asserted that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of "pseudoaddiction."

c. Endo trained its sales representatives to distinguish addiction from "pseudoaddiction." The NYAG reached a settlement with Endo in 2016 regarding this representation and others, finding that "the 'pseudoaddiction' concept has

never been empirically validated and in fact has been abandoned by some of its proponents."

4. Janssen

a. From 2009 to 2011, Janssen's website *Let's Talk Pain* stated that "pseudoaddiction … refers to patient behaviors that may occur when pain is under-treated" and that "[p]seudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."

5. Mallinckrodt

a. Mallinckrodt sponsored FSMB's Responsible Opioid Prescribing (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding opioids, are all signs of "pseudoaddiction." Mallinckrodt spent at least $100,000 to support distribution of the book to state medical boards.

6. Purdue

a. Purdue published a prescriber and law enforcement education pamphlet titled Providing Relief, Preventing Abuse (2011), which described "pseudoaddiction" as a concept that "emerged in the literature to describe the inaccurate interpretation of [addictive drug-seeking behaviors] in patients who have pain that has not been effectively treated.

b. Purdue distributed to physicians, and posted on its unbranded website Partners Against Pain, a pamphlet titled Clinical Issues in Opioid Prescribing (2006). This pamphlet included a list of conduct, including "illicit drug use and deception," that it defined as indicative of "pseudoaddiction" or

undertreated pain. It also stated: "Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when pain is undertreated.... Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated."

c. Purdue sponsored FSMB's Responsible Opioid Prescribing (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding opioids, are all signs of "pseudoaddiction." Purdue also spent over $100,000 to support distribution of the book.

d. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management (2011), which stated: "Pseudo-addiction describes patient behaviors that may occur when pain is undertreated.... Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated."

E. In Their Deceptive Marketing, the Marketing Conspirators and Their Third Party Allies Claimed that Opioid Withdrawal Symptoms Can Be Readily Managed

482. In an effort to further downplay the risks and devastating impact of addiction. The Marketing Conspirators and their Third Party Allies frequently claimed that, while patients become "physically" dependent on opioids, physical dependence can be adequately addressed by gradually tapering patients' doses to avoid the adverse effects of withdrawal. The Marketing Conspirators and their Third Party Allies promoted this false and misleading message so that prescribers and patients would be more likely to initiate long-term opioid therapy and would fail

to recognize the actual risk of addiction.

483. The Marketing Conspirators failed to properly disclose that discontinuing long-term use of opioids can be very difficult. These effects make it less likely that patients will be able to stop using opioids.

484. In truth, physiological dependence on opioids starts to develop after a few days of regular use. Common withdrawal symptoms include severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, and pain, among other things.

485. Some symptoms may persist for months, or even years, after a complete withdrawal from opioids, depending on how long the patient had been using opioids. Withdrawal symptoms trigger a feedback loop that drives patients to return to opioids.

486. Each of the Marketing Conspirators' representations below falsely states or suggests that opioid withdrawal is manageable, so that physicians and users would increase opioid use.

487. These misrepresentations, which were intended to persuade prescribers, patients, and third-party payors to choose opioids over competing medications and therapies, were likely to, and did, confuse, deceive, and mislead Marketing Conspirators' target audience about the difficult of treating and managing withdrawal in opioid users. These misrepresentations were not only likely to, but did in fact, make a difference in the purchasing and prescribing decisions of patients, doctors, and other third-party payors. The Marketing Conspirators' misleading marketing was intended to minimize the reality of managing withdrawal symptoms, and thereby encourage the public to choose opioids over other pain relief therapies and to continue taking, prescribing, or paying for opioids when used to treat long-term pain.

488. The misrepresentations included the following:

1. Actavis

a. Documents from a 2010 sales training indicate that Actavis trained its sales force to convey that discontinuing opioid therapy can be handled "simply" and that it can be done at home. Actavis' sales representative training also claimed that opioid withdrawal would take only a week, even in addicted patients.

2. Endo

a. A CME sponsored by Endo, titled Persistent Pain in the Older Adult, taught that withdrawal symptoms can be avoided entirely by tapering the dose by 10-20% per day for ten days.

3. Janssen

a. A Janssen PowerPoint presentation used for training its sales representatives titled Selling Nucynta ER indicated that the "low incidence of withdraw symptoms" is a "core message" for its sales force. This message was repeated in numerous Janssen training materials between at least 2009 and 2011. The studies purportedly supporting this claim did not describe withdrawal symptoms in patients taking Nucynta ER beyond 90 days or at high doses, and would therefore not be representative of withdrawal symptoms in the patient population taking long-term opioids. Patients on long-term treatment will have a harder time discontinuing the drugs and are more likely to experience withdrawal symptoms. In addition, in claiming a low rate of withdrawal symptoms, Janssen relied on a study that only began tracking withdrawal symptoms in patients two to four days after discontinuing opioid use. Janssen knew or should have known that

these symptoms peak earlier than that for most patients. Relying on data after that initial window of severe withdrawal symptoms painted a misleading picture of the likelihood and severity of withdrawal associated with long-term opioid therapy. Janssen also knew or should have known that patients involved in the study were not taking the drug long enough to develop rates of withdrawal symptoms comparable to withdrawal symptoms suffered by patients who use opioids for chronic pain – a use for which Janssen promoted Nucynta ER.

b. Janssen sales representatives told prescribers that patients on Janssen's opioid drugs were less susceptible to withdrawal than those on other opioids.

4. Purdue

a. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management (2011), which taught that "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but did not disclose the significant hardships that often accompany cessation of use.

b. Purdue sales representatives told prescribers that the potential for withdrawal on Butrans was low due to Butrans' low potency and its extended release mechanism.

c. In 2007, Purdue pleaded guilty to criminal charges stemming from its misleading marketing and promotion of OxyContin as having manageable withdrawal symptoms. Purdue admitted that it misrepresented to doctors that "patients could stop therapy abruptly without experiencing withdrawal symptoms

and that patients who took OxyContin would not develop tolerance to the drug."

d. On information and belief, Purdue sales representatives told prescribers that the effects of withdrawal from opioid use can be reasonably managed.

F. In Their Deceptive Marketing, the Marketing Conspirators and Their Third Party Allies Improperly Minimized the Risks of Increased Doses of Opioids

489. As part of their marketing campaign, the Marketing Conspirators and their Third Party Allies also claimed that prescribers and patients could increase doses of opioids indefinitely without added risk, even when pain was not decreasing or when doses had reached levels that were "frighteningly high." The Marketing Conspirators suggested that patients would eventually reach a stable, effective dose as the dosage strength increased.

490. Each of the Marketing Conspirators' representations also omitted warnings of increase adverse effects that occur at higher doses, and misleadingly suggested that there was no greater risk to higher dose opioid therapy.

491. The Marketing Conspirators made these misleading representations and omissions about the known risks of higher doses of opioids so that prescribers and patients would be more likely to continue to prescribe and use opioids. The misrepresentations also helped persuade physicians and patients not to discontinue opioids when patients' increased tolerance required them to seek higher doses.

492. In fact, patients receiving increasingly higher doses of opioids as part of long-term opioid therapy are three to nine times more likely to suffer an overdose than those on low doses. As compared to non-opioid pain remedies, an opioid patient's tolerance to pain-reducing properties of opioids develops faster than tolerance to the adverse respiratory effects of opioids. Thus, the practice of continuously escalating opioid doses to match pain tolerance can, in fact,

lead to overdose due to respiratory complications even where opioids are taken as recommended in line with a patient's pain needs.

493. Moreover, it is harder for patients to terminate use of higher-dose opioids without severe withdrawal effects. This contributes to a cycle of continued use, even when the drugs provide diminishing pain relief and are causing harm.

494. Each of the representations from the Marketing Conspirators and their Third Party Allies misleadingly minimized the risks that increased doses of opioids pose to patients. These misrepresentations were likely to, and did – as intended – confuse, deceive, and mislead the Marketing Conspirators' target audience about the risks associated with higher doses of opioids to treat chronic pain. These misrepresentations and omissions were not only likely to, and intended to, but did in fact, make a difference in the purchasing and prescribing decisions of patients, doctors, and other third-party payors, as the Marketing Conspirators' misleading marketing promoted the message that patients would not be at risk if they continued to increase their doses of opioids. This misleading message influenced Marketing Conspirators' target audience to choose opioids over other, non-opioid treatments and medications.

495. The misrepresentations included the following:

1. Actavis

a. Documents from a 2010 sales training indicate that Actavis trained its sales force that "individualization" of opioid therapy depended on increasing doses "until patient reports adequate analgesia" and to "set dose levels on [the] basis of patient need, not on [a] predetermined maximal dose." Actavis further counseled its sales representatives that the reasons some physicians had for not increasing doses indefinitely were simply a matter of physician "comfort level,"

which could be overcome or used as a tool to induce them switch to Actavis' opioid, Kadian.

2. Cephalon

a. Cephalon sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which claimed that some patients "need" a larger dose of their opioid, regardless of the dose currently prescribed.

b. Cephalon sponsored a CME written by KOL Dr. Webster, titled Optimizing Opioid Treatment for Breakthrough Pain, which was offered online by Medscape, LLC in 2007 and 2008. The CME taught that non-opioid analgesics and combination opioids that include aspirin and acctaminophen are less effective to treat breakthrough pain because of dose limitations, implying that patients benefited from less restrictive dose limitations.

c. On information and belief, Cephalon sales representatives assured prescribers that opioids were safe, even at high doses.

3. Endo

a. Endo sponsored a website, painknowledge.com, through APF and NIPC, which in 2009 claimed that opioids may be increased until "you are on the right dose of medication for your pain." Endo funded the site, which was a part of Endo's marketing plan, and tracked visitors to it.

b. Endo distributed a patient education pamphlet edited by KOL Dr. Portenoy titled Understanding Your Pain. Taking Oral Opioid Analgesics (2004). In Q&A format, it asked: "If I take the opioid now, will it work later when I really need it?" The response was: "The dose can be increased .... You won't 'run out'

of pain relief."

4. Insys

a. Despite its public statements to the contrary, Insys aggressively and deceptively marketed Subsys in order to push prescribers to write initial Subsys prescriptions above the allowed 100 mcg dosage. This marketing was in direct contravention of the FDA-approved label for initial prescriptions of Subsys and in blatant disregard of the danger to patients taking Subsys. Insys made numerous false and deceptive statements to further this scheme, including fraudulent misrepresentations to insurers.

b. Insys sales representatives minimized the risks of Subsys to patients like Sarah Fuller, and to her Subsys prescriber, both of whom Insys misled about the safety and efficacy of Subsys.

c. Within a year of Insys's direct misrepresentations to her and her physician, Ms. Fuller died of a Subsys-related overdose at the age of 32.

5. Janssen

a. Janssen sponsored a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009), which its personnel reviewed and approved and its sales force distributed. This guide listed dose limitations as "disadvantages" of other pain medicines and omitted any discussion of risks of increased doses of opioids.

6. Purdue

a. Through at least June 2015, Purdue's website In the Face of Pain, along with initiatives of APF, promoted the notion that if a patient's doctor does

not prescribe what – in their view – is a sufficient dose of opioids, they should find another doctor who will increase the dosage. In so doing, Purdue exerted influence over prescribers who face pressure to accede to the patients' demands for increased dosages.

b. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which taught that dose escalations are "sometimes necessary," even indefinitely high ones. This falsely suggested that high dose opioids are safe and appropriate. It did not disclose the risks from high dose opioids.

c. Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which taught patients that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The guide also claimed that some patients "need" a larger dose of the drug, regardless of the dose currently prescribed. This language failed to disclose the heightened risks at elevated doses.

d. Purdue sponsored a CME issued by the American Medical Association in 2007, 2010, and 2013. The CME, titled Overview of Pain Management Options, was edited by KOL Dr. Portenoy, among others, and taught that other drugs, but not opioids, are unsafe at high doses.

e. Purdue sales representatives told prescribers that high-dose opioid were effective for treating patients long-term, and omitted any discussion that increased tolerance would require increase – and increasingly dangerous – doses.

G. In Their Deceptive Marketing of Opioids, the Marketing Conspirators and Their Third Party Allies Materially Overstated the Risks of Alternative Forms of Pain Treatment

496. The Marketing Conspirators and their Third Party Allies also misleadingly emphasized or exaggerated the risks of alternative therapies, such as non-opioid analgesics. These misrepresentations, which were intended to persuade prescribers, patients, and health care payors to choose opioids over competing medications and therapies, were likely to, and did, confuse, deceive, and mislead Marketing Conspirators' target audience about the purported inferiority and dangers of non-opioid pain medications.

497. Further, these misrepresentations were not only likely to, but did in fact, make a difference in the purchasing and prescribing decisions of patients, doctors, and other third-party payors, as the Marketing Conspirators' misleading marketing was *specifically designed* to encourage the purchasing, prescribing, and reimbursing public to choose opioids over other pain relief therapies.

498. In connection with their inaccurate and unsupported emphasis on the purported risks of non-opioid products, the Marketing Conspirators and their Third Party Allies routinely minimized or ignored the risks of long-term opioid therapy. These opioid risks – which are in addition to the life-threatening risks associated with misuse, abuse, and addiction – include: hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;"[218] hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; NAS (when an infant exposed to opioids withdraws from the drugs after birth); and potentially fatal interactions with alcohol and benzodiazepines which are

[218] Woodcock Ltr., Sept. 10, 2013, *supra* note 205.

used to treat post-traumatic stress disorder and anxiety (disorders frequently coexisting with chronic pain conditions), and other drugs.

499. Despite these serious risks, the Marketing Conspirators asserted or implied that opioids were appropriate first-line treatments and safer than alternative non-opioid treatments, including non-steroidal anti-inflammatory drugs ("NSAIDs") such as ibuprofen (Advil, Motrin) or naproxen (Aleve). While NSAIDs can pose gastrointestinal, renal, and cardiac risks, particularly for elderly patients, the Marketing Conspirators' exaggerated descriptions of those risks were improper, and made their omissions minimizing opioid risks all the more misleading.

500. As part of this marketing ploy, the Marketing Conspirators and their Third Party Allies described over-the-counter NSAIDs as life-threatening and falsely asserted that they were responsible for 10,000 to 20,000 deaths annually (more than opioids), when in truth the number is closer to 3,200.[219]

501. The Marketing Conspirators' description of NSAID risks starkly contrasted with Marketing Conspirators' representation of opioid risks, which, according to the Marketing Conspirators, included mostly mild conditions such as nausca, constipation, and sleepiness (but not addiction, overdose, or death). In fact, compared with NSAIDs, prescription opioids are responsible for approximately five times as many fatalities annually.

502. As with the Marketing Conspirators' other misrepresentations as alleged more fully herein, the Marketing Conspirators' misleading claims regarding the comparative risks of NSAIDs and opioids had the effect of shifting the balance of opioids' risks and purported benefits. While the volume of opioid prescriptions has exploded over the past two decades, the

[219] https://ce4*l*ess.com/Tests/Materials/E019Materials.pdf at pg. 10; *see also* https://www.practicalpainmanagement.com/treatments/pharmacological/opioids/ask-expert-do-nsaids-cause-more-deaths-opioids.

use of NSAIDs has declined during that same time.[220]

503. Each of the following representations reflects (but does not exhaustively list) the deceptive claims and omissions by the Marketing Conspirators and their Third Party Allies about the risks of opioids relative to NSAIDs:

1. Actavis

a. Documents from a 2010 sales training indicate that Actavis trained its sales force that the ability to escalate doses during long-term opioid therapy, without hitting a dose ceiling, made opioid use safer than other forms of therapy that had defined maximum doses, such as acetaminophen or NSAIDs.

b. Actavis also trained physician-speakers that "maintenance therapy with opioids can be safer than long-term use of other analgesics," including NSAIDs, for older persons.

c. On information and belief, Actavis sales representatives told prescribers that NSAIDs were less beneficial or more risky than opioids.

2. Cephalon

a. Cephalon sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which taught patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication attributed 10,000 to 20,000 deaths annually to NSAID overdose. Treatment Options also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids.

[220] https://fitness.mercola.com/sites/fitness/archive/2013/08/16/back-pain-overtreatment.aspx

b. On information and belief, Cephalon sales representatives told prescribers that NSAIDs were less beneficial or more risky than opioids.

3. Endo

a. Endo distributed a "case study" to prescribers titled Case Challenges in Pain Management: Opioid Therapy for Chronic Pain. The study cited an example, meant to be representative, of a patient with a massive upper gastrointestinal bleed believed to be related to his protracted use of NSAIDs" (over eight years). The study recommended treating the patient with opioids instead.

b. Endo sponsored a website, painknowledge.com, through APF and NIPC, which contained a flyer titled Pain: Opioid Therapy. This publication included a list of adverse effects from opioids that omitted significant adverse effects like hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance dependence, addiction, and death. Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it.

c. Endo provided grants to APF to distribute the book *Exit Wounds* (2009), which omitted warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids.

d. On information and belief, Endo sales representatives told prescribers that NSAIDs were less beneficial or more risky than opioids.

4. Janssen

a. Janssen sponsored a patient education guide titled Finding Relief: Pain Management for Older Adults (2009), which its personnel reviewed and approved and its sales force distributed. This publication described the advantages and disadvantages of NSAIDs on one page, and the "myths/facts" of opioids on the facing page. The disadvantages of NSAIDs are described as involving "stomach upset or bleeding," "kidney or liver damage if taken at high doses or for a long time," "adverse reactions in people with asthma," and "increase [in] the risk of heart attack and stroke." The only adverse effects of opioids listed are "upset stomach or sleepiness" (which the brochure claims will dissipate), and constipation.

b. Janssen sponsored APF's book *Exit Wounds* (2009), which omits warning of the risk of interactions between opioids and benzodiapenies. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids.

c. Janssen sales representatives told prescribers that Nucynta was not an opioid, making it a good choice for chronic pain patients who previously were unable to continue opioid therapy due to excessive side effects. This statement was misleading because Nucynta is, in fact, an opioid and has the same effects as other opioids.

d. On information and belief, Janssen sales representatives told prescribers that NSAIDs were less beneficial or more risky than opioids.

5. Purdue

a. Purdue sponsored APF's book *Exit Wounds* (2009), which omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids.

b. Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which advised patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication attributes 10,000 to 20,000 deaths annually to NSAID overdose. Treatment Options also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids.

c. Purdue sponsored a CME issued by the American Medical Association in 2007, 2010, and 2013. The CME, titled Overview of Management Options, was edited by KOL Dr. Portenoy, among others and taught that NSAIDs, but not opioids, are unsafe at high doses.

d. On information and belief, Purdue sales representative told prescribers that NSAIDs were less beneficial or more risky than opioids.

VIII. The Marketing Conspirators Conspired to Deceptively Market Opioids

504. As alleged above, at all relevant times, the Marketing Conspirators, together with their Third Party Allies and each other, expanded the market for prescription opioids through a fraudulent and deceptive marketing campaign that over-emphasized the under-treatment of pain

and deceptively marketed opioids as being: (i) rarely, if ever, addictive; (ii) safer and more effective for the treatment of chronic long-term pain than indicated by the data; (iii) abuse resistant or deterrent; or (iv) safe and effective for other types of pain for which the drugs were not approved.

505. For the purpose of maximizing revenue, sales, and profit, the Marketing Conspirators unlawfully agreed, with their Third Party Allies and each other, to deceive opioid prescribers and the public into believing that opioids were safer and more effective for the treatment of long-term chronic pain than they were, and presented minimal risk of addiction. In doing so, they sought to maximize revenues from the design, manufacture, distribution and sale of opioids which, in fact, were highly addictive and often ineffective and dangerous when used for long term, chronic and other types of pain.

506. As a direct and proximate result of their fraudulent scheme and common course of conduct, the defendants were able to extract revenues of billions of dollars. As discussed below, the Marketing Conspirators' years-long misconduct violated state and federal law.

507. The Marketing Conspirators were systematically linked to each other through corporate ties, contractual relationships, financial ties and continuing coordination of activities. The Marketing Conspirators shared a common purpose of increasing their revenues and market share, and minimizing losses. Purdue, Cephalon, Endo, Actavis, and Mallinckrodt shared in the bounty by sharing the benefit derived from increased sales of opioids and other revenue generated by the scheme to defraud prescribers and consumers in Allentown.

508. The Marketing Conspirators engaged in, indeed, continue to engage in the deceptive marketing of opioids as non-addictive, and as safer and more effective for chronic long-term pain than they actually are.

509. The Marketing Conspirators have engaged in such activity for the purpose of maximizing the sale and profits of opioids.

510. To fulfill this purpose, Defendants Purdue, Cephalon, Endo, Actavis, and Mallinckrodt have advocated for and caused the overprescription of opioids by marketing, promoting, advertising and selling opioids in Allentown.

511. As detailed above, the Marketing Conspirators relentlessly promoted opioids as having little to no risk of addiction, as being both safe and effective for the treatment of long-term chronic pain. The Marketing Conspirators' success in maximizing sales was due to the tight collaboration among themselves through and in collaboration with the pain foundations – a formidable partnership that marketed to hundreds of thousands of prescribers across the country, including prescribers in the City.

512. On numerous occasions, the Marketing Conspirators funded the pain foundations' marketing efforts. The Marketing Conspirators specifically chose to partner with the pain foundations and individual physicians to publish and otherwise disseminate misleading pro-opioid material, knowing the public and prescribers would be more receptive to statements made by what they perceived to be scholarly, neutral, third party sources.

513. The Marketing Conspirators worked together to further the conspiracy, by and among the following manner and means:

a. jointly planning to deceptively market and manufacture opioids that were purportedly non-addictive and safer and more effective for the treatment of chronic, long-term pain than they actually were;

b. concealing the addictive qualities of the opioids from prescribers and the public;

c. misleading the public about the addictive quality and safety and efficacy of opioids;

d. otherwise misrepresenting or concealing the highly dangerous nature of opioids from prescribers and the public;

e. materially overstating the risks of alternative forms of pain treatment;

f. illegally marketing, selling and/or distributing opioids; and

g. profiting from the sale of such products for uses for which they are unapproved, unsafe or ineffective.

514. To achieve their common goals, the Marketing Conspirators hid from the general public the full extent of the unsafe and often ineffective nature of opioids for chronic pain as described herein. The Marketing Conspirators also suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities about the addictive, unsafe and often ineffective nature of opioids.

515. The foregoing allegations support that the Marketing Conspirators acted in concert, with a common purpose, in knowingly and intentionally engaging in deceptive marketing practices, and incentivizing pain foundations, marketing firms and physicians to do so as well.

516. To achieve their common goals, the Marketing Conspirators devised and knowingly carried out a material scheme and/or artifice to defraud regulators, prescribers, patients, and the public to obtain money from Allentown by means of materially false or fraudulent pretenses, representations, promises or omissions of material facts.

517. To carry out and attempt to carry out the scheme to defraud, the Marketing

Conspirators employed the use of the mail and wire facilities, in violation of 18 U.S.C. §§1341 (mail fraud), 1343 (wire fraud), and 1349 (conspiracy to commit mail and wire fraud). The Marketing Conspirators' use of the mails and wires (or causing the issue thereof) include, but are not limited to, the transmission, delivery and shipment of deceptive marketing materials. These materials, which would not have been delivered but for the fraudulent scheme, include but were not limited to:

a. the FSMB's publication of opioid prescribing guidelines entitled "Responsible Opioid Prescribing," by Fishman;

b. the FSMB's publication of "Revised and Expanded 2nd Edition [of] Responsible Opioid Prescribing[:] A Guide for Florida Clinicians";

c. the APF's publication of *Exit Wounds*;

d. the AAPM's "consensus statement" and educational programs featuring Fine;

e. the APA's publication and dissemination of "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse";

f. false or misleading communications to the public and to regulators;

g. sales and marketing materials, including slide decks, presentation materials, purported guidelines, advertising, web sites, product packaging, brochures, labeling and other writings which misrepresented, falsely promoted and concealed the true nature of opioids;

h. documents intended to facilitate the manufacture and sale of opioids, including bills of lading, invoices, shipping records, reports and correspondence;

i. documents to process and receive payment for opioids, including invoices and receipts;

j. payments to the foundations and physicians that deceptively marketed the Marketing Conspirators' opioids;

k. deposits of proceeds; and

l. other documents and things, including electronic communications.

IX. The Defendants Failed to Guard Against Unlawful Diversion as Required by Pennsylvania and Federal Law

518. The residents of Allentown, like all Americans, have a common right to be free from conduct that creates an unreasonable danger to their health, welfare, property and safety. As such, they are further entitled to expect that the regulated system for distributing dangerous and addictive narcotics will be kept closed. As distributors of prescription opioids, all Defendants owed a duty to keep distribution within the closed system and to prevent unlawful diversion into cities including Allentown.

519. Multiple sources impose duties on the Defendants to report suspicious orders and further to not ship those orders unless due diligence disproves those suspicions.

520. First, under the common law, all Defendants had a duty to exercise reasonable care in delivering dangerous narcotic substances. By flooding Pennsylvania with more opioids than could be used for legitimate medical purposes and by filling and failing to report orders that they knew or should have realized were likely being diverted for illicit uses, Defendants breached that duty and both created and failed to prevent a foreseeable risk of harm.

521. Second, each of the Defendants assumed a duty, when speaking publicly about opioids and their efforts to combat diversion, to speak accurately and truthfully.

522. Third, each of the Defendants was required to register with the DEA to

manufacture and/or distribute Schedule II controlled substances. *See* 21 U.S.C. § 823(a)-(b), (e); 28 C.F.R. §0.100. As registrants, Defendants were required to "maint[ain] . . . effective controls against diversion" and to "design and operate a system to disclose . . . suspicious orders of controlled substances." 21 U.S.C. § 823(a)-(b); 21 C.F.R. § 1301.74. Defendants were further required to take steps to halt suspicious orders. Defendants violated their obligations under federal law.

523. Fourth, as described below, Defendants also had duties under applicable state laws.

524. Recognizing a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970. The CSA and its implementing regulations created a closed- system of distribution for all controlled substances and listed chemicals. Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market. Congress was concerned with the diversion of drugs out of legitimate channels of distribution and acted to halt the "widespread diversion of [controlled substances] out of legitimate channels into the illegal market." Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain. All registrants—which includes all manufacturers and distributors of controlled substances (including all Defendants here)—must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion. When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse. The result is the scourge of addiction that has occurred.

525. The CSA requires manufacturers and distributors of Schedule II substances like opioids to: (a) limit sales within a quota set by the DEA for the overall production of Schedule II substances like opioids; (b) register to manufacture or distribute opioids; (c) maintain effective controls against diversion of the controlled substances that they manufacture or distribute; and (d) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA.

526. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from "legitimate channels of trade" by controlling the "quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs." When evaluating production quotas, the DEA was instructed to consider the following information:

a. Information provided by the Department of Health and Human Services;
b. Total net disposal of the basic class [of each drug] by all manufacturers;
c. Trends in the national rate of disposal of the basic class [of drug];
d. An applicant's production cycle and current inventory position;
e. Total actual or estimated inventories of the class [of drug] and of all substances manufactured from the class and trends in inventory accumulation; and
f. Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.

527. It is unlawful to manufacture a controlled substance in Schedule II, like prescription opioids, in excess of a quota assigned to that class of controlled substances by the DEA.

528. To ensure that even drugs produced within quota are not diverted, federal regulations issued under the CSA mandate that all registrants, manufacturers and distributors alike, "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). Registrants are not entitled to be passive observers, but rather "shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant." *Id*. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. *Id*. Other red flags may include, for example, "[o]rdering the same controlled substance from multiple distributors."

529. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a distributor or manufacturer need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of the industry. For this reason, identification of suspicious orders serves also to identify excessive volume of the controlled substance being shipped to a particular region.

530. In sum, Defendants have several responsibilities under state and federal law with respect to control of the supply chain of opioids. First, they must set up a system to prevent diversion, including excessive volume and other suspicious orders. That would include reviewing their own data, relying on their observations of prescribers and pharmacies, and

following up on reports or concerns of potential diversion. All suspicious orders must be reported to relevant enforcement authorities. Further, they must also stop shipment of any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, they can determine that the order is not likely to be diverted into illegal channels.

531. State and federal statutes and regulations reflect a standard of conduct and care below which reasonably prudent manufacturers and distributors would not fall. Together, these laws and industry guidelines make clear that Distributor Defendants and Marketing Conspirators alike possess and are expected to possess specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the diversion of prescription narcotics when the supply chain is not properly controlled.

532. Further, these laws and industry guidelines make clear that the Distributor Defendants and Marketing Conspirators alike have a duty and responsibility to exercise their specialized and sophisticated knowledge, information, skill, and understanding to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market.

533. The Federal Trade Commission ("FTC") has recognized the unique role of distributors. Since their inception, Distributor Defendants have continued to integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products and health care supplies. In addition to the actual distribution of pharmaceuticals, as wholesalers, Distributor Defendants also offer their pharmacy, or dispensing, customers a broad range of added services. For example, Distributor Defendants offer their pharmacies sophisticated ordering systems and access to an inventory management system and distribution facility that

allows customers to reduce inventory carrying costs. Distributor Defendants are also able to use the combined purchase volume of their customers to negotiate the cost of goods with manufacturers and offer services that include software assistance and other database management support. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC's motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the potential anti-competitive effect of a proposed merger between Cardinal Health, Inc. and Bergen Brunswig Corp.). As a result of their acquisition of a diverse assortment of related businesses within the pharmaceutical industry, as well as the assortment of additional services they offer, Distributor Defendants have a unique insight into the ordering patterns and activities of their dispensing customers.

534. Marketing Conspirators also have specialized and detailed knowledge of the potential suspicious prescribing and dispensing of opioids through their regular visits to doctors' offices and pharmacies, and from their purchase of data from commercial sources, such as IMS Health. Their extensive boots-on-the-ground activity through their sales force allows Marking Defendants to observe the signs of suspicious prescribing and dispensing discussed elsewhere in the Complaint—lines of seemingly healthy patients, out-of-state license plates, and cash transactions, to name only a few. In addition, Marketing Conspirators regularly mined data, including, upon information and belief, chargeback data, which allowed them to monitor the volume and type of prescribing of doctors, including sudden increases in prescribing and unusually high dose prescribing, which would have alerted them, independent of their sales representatives, to suspicious prescribing. These information points gave all Defendants insight into prescribing and dispensing conduct that enabled them to play a valuable role in the preventing diversion and fulfilling their obligations under the CSA.

535. Defendants have a duty, and are expected, to be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.

536. Defendants breached these duties by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities they knew or should have known could not be justified and were indicative of serious problems of overuse of opioids.

537. By unlawfully, recklessly, and intentionally distributing opioids without maintaining effective controls against diversion, Defendants have caused widespread distribution of prescription opioids in and/or to Allentown, resulting in increased levels of injury, death, addiction, abuse, crime, fear, discomfort and inconvenience, all at great cost to the City. As alleged herein, Defendants' conduct was illegal.

A. The Distributor Defendants' Unlawful Failure to Prevent Diversion and Monitor, Report, and Prevent Suspicious Orders

538. The Distributor Defendants owe a duty under both federal law and Pennsylvania law to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating from Plaintiff's Community as well as those orders which the Distributor Defendants knew or should have known were likely to be diverted into Plaintiff's Community.

539. The foreseeable harm from a breach of these duties is the diversion of prescription opioids for nonmedical purposes.

540. Each Distributor Defendant repeatedly and purposefully breached its duties under state and federal law. Such breaches are a direct and proximate causes of the widespread diversion of prescription opioids for nonmedical purposes into Plaintiff's Community.

541. The unlawful diversion of prescription opioids is a direct and proximate cause and/or substantial contributing factor to of the opioid epidemic, prescription opioid abuse,

addiction, morbidity, and mortality in the State and in Plaintiff's Community. This diversion and the epidemic are direct causes of harms for which Plaintiff seeks to recover here.

542. The opioid epidemic in the State, including *inter alia* in Plaintiff's Community, remains an immediate hazard to public health and safety.

543. The opioid epidemic in Plaintiff's Community is a continuous public nuisance and remains unabated.

544. The Distributor Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

1. Distributors Had a Duty under State and Federal Law to Guard Against, and Report, Unlawful Diversion and to Report and Prevent Suspicious Orders

545. Under federal and Pennsylvania law, all or nearly all prescription opioids are classified as Schedule II controlled substances because they have a "high potential for abuse" and the potential to cause "severe psychic or physical dependence" and/or "severe psychological . . . dependence." 21 U.S.C. § 812(b)(2)(A),(C); 35 P.S. §§ 780-104; 28 Pa. Code § 25.72.

546. As wholesale drug distributors in Pennsylvania, each Defendant was subject to both the Pennsylvania Controlled Substances Act ("PCSA"), 35 Pa.C.S.A. § 780, et seq. and the Federal Controlled Substances Act, 21 U.S.C. §801, et seq. Distributor Defendants are also subject to both the Pennsylvania Wholesale Prescription Drug Distributors License Act ("Pennsylvania WPDDLA"), 63 P.S. §391.6, et seq.

547. Each Distributor Defendant was further required to register with the DEA, pursuant to the federal Controlled Substance Act. *See* 21 U.S.C. § 823(b), (e); 28 C.F.R. § 0.100. Each Distributor Defendant is a "registrant" as a wholesale distributor in the chain of distribution

of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme.

548. Each Distributor Defendant has an affirmative duty under federal and Pennsylvania law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that distributors of Schedule II drugs, including opioids, must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. §§ 823(b)(1). As discussed below, those requirements are adopted and incorporated into Pennsylvania law.

549. These regulations impose a non-delegable duty upon wholesale drug distributors to design and execute systems for discovering "suspicious orders" of opioids, which must then be reported to the DEA. See 21 C.F.R. § 1301.74(b) (explaining this duty).

550. Federal regulations provide a non-exhaustive list of examples of suspicious orders: "orders of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern." 21 C.F.R. § 1301.74(b). These criteria are disjunctive and are not all-inclusive.

551. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious.

552. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the wholesale

distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

553. In addition to reporting all suspicious orders, distributors also must stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, No. 15-11355 (D.C. Cir. June 30, 2017). Regardless, all flagged orders must be reported. *Id.*

554. These prescription drugs are regulated for the purpose of providing a "closed" system intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[221]

555. Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant's role and responsibilities.[222]

556. As the DEA advised the Distributor Defendants in a letter to them dated September 27, 2006, wholesale distributors are "one of the key components of the distribution

[221] *See* 1970 U.S.C.C.A.N. 4566, 4571-72.

[222] Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enf't Admin.* (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at *22 [hereinafter Brief for HDMA and NACDS]. The Healthcare Distribution Management Association (HDMA or HMA)—now known as the Healthcare Distribution Alliance ("HDA") — is a national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. *See generally* HDA, *About*, https://www.healthcaredistribution.org/about (last visited Aug. 13, 2019). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies. *See generally* NACDS, *Mission*, https://www.nacds.org/ about/mission/ (last visited Aug. 13, 2019).

chain. If the closed system is to function properly … distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as … the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[223]

557. The Distributor Defendants have admitted that they are responsible for reporting suspicious orders. [224]

558. The DEA sent a letter to each of the Distributor Defendants on September 27, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, in addition to reporting suspicious orders, has a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[225] The letter also instructs that "distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes."[226] The DEA warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm." [227]

559. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007.[228] This letter reminds the Distributor Defendants of their statutory and regulatory

[223] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Letter] ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces."), *filed in Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.
[224] *See* Brief for HDMA and NACDS, 2016 WL 1321983, at *4 ("[R]egulations . . . in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders).").
[225] Rannazzisi Letter, at 2.
[226] *Id*. at 1.
[227] *Id*. at 2.
[228] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin.,

duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances." [229]

560. The letter further explains:

> The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.
>
> The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the segment of the regulated industry.
>
> Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually

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U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8.

[229] *Id*.

> large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.
>
> When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."
>
> Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest, as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.[230]

561. Finally, this second DEA letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 FR 36487-01, 2007 WL 1886484 (July 3, 2007), which discusses "the obligation to report suspicious orders[,]. . . some criteria to use when determining whether an order is suspicious[, and]… your obligation to maintain effective controls against the diversion of controlled substances." [231] Finding Southwood Pharmaceuticals, Inc.'s continued ability to distribute opioid hydrocodone to be "an imminent danger to public health and safety," the DEA noted that "the abuse of controlled prescription drugs in America now eclipses abuse of all illicit drugs combined, except marijuana."[232] The opioid epidemic has only escalated in the ensuing decade.

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[230] *Id*.
[231] *Id*.
[232] 2007 WL 1886484 at *36504 (July 3, 2007).

562. The Distributor Defendants admit that they "have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."[233]

563. The Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." The guidelines set forth recommended steps in the "due diligence" process, and note in particular: If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.[234]

564. Each of the Distributor Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers in Plaintiff's Community and/or to retailers from which Defendants knew prescription opioids were likely to be diverted to Plaintiff's Community.

565. Each Distributor Defendant owes a duty to monitor and detect suspicious orders of prescription opioids.

566. Each Distributor Defendant owes a duty under federal and state law to investigate and refuse suspicious orders of prescription opioids.

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[233] *See* Brief of HDMA, 2012 WL 1637016, at *2.

[234] Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B).

567. Each Distributor Defendant owes a duty under federal and state law to report suspicious orders of prescription opioids.

568. Each Distributor Defendant owes a duty under federal and state law to prevent the diversion of prescription opioids into illicit markets in the State and Plaintiff's Community.

569. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and subsequent plague of opioid addiction.

570. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is the devastation described above, and the damages caused thereby.

2. The Distributor Defendants Breached Their Legal Duties

571. Because distributors handle such large volumes of controlled substances and are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system collapses.[235]

572. The sheer volume of prescription opioids distributed to pharmacies in Plaintiff's Community, and/or to pharmacies from which the Distributor Defendants knew the opioids were likely to be diverted into Plaintiff's Community, is excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them. [236]

573. Additionally, the Distributor Defendants' grossly negligent distribution to pharmacies outside Plaintiff's Community also caused an influx of illicit diversion of opioids

[235] *See* Rannazzisi Decl. ¶ 10, filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.
[236] *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,316, 62,322 (2012)).

within Plaintiff's Community, including Allentown.

574. The Distributor Defendants failed to report "suspicious orders" originating from Plaintiff's Community, or which the Distributor Defendants knew were likely to be diverted to Plaintiff's Community, to the federal and state authorities, including the DEA and/or the state Board of Pharmacy.

575. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency in Plaintiff's Community, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to Plaintiff's Community.

576. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse, and report suspicious orders of prescription opioids originating from Plaintiff's Community, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to Plaintiff's Community.

577. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opioids into other than legitimate medical, scientific, and industrial channels.

578. The Distributor Defendants breached their duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and failed to inform the authorities including the DEA of suspicious orders when discovered, in violation of their duties under federal and state law.

579. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical,

scientific, and industrial channels.[237]

580. The federal and state laws at issue here are public safety laws.

581. The Distributor Defendants' violations of public safety statutes constitute *prima facie* evidence of negligence under State law.

582. The Distributor Defendants supplied prescription opioids to obviously suspicious physicians and pharmacies, enabled the illegal diversion of opioids, aided criminal activity, and disseminated massive quantities of prescription opioids into the black market.

583. The unlawful conduct by the Distributor Defendants is purposeful and intentional. The Distributor Defendants refuse to abide by the duties imposed by federal and state law which are required to legally acquire and maintain a license to distribute prescription opioids.

584. The Distributor Defendants acted with actual malice in breaching their duties, *i.e.*, they have acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

585. The Distributor Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

3. The Distributor Defendants Sought to Avoid and Misrepresent their Compliance with Their Legal Duties

586. The Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under state and federal law and have wrongfully and repeatedly disavowed

[237] *See Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

those duties in an effort to mislead regulators and the public regarding the Distributor Defendants' compliance with their legal duties.

587. Distributor Defendants have publicly and forcefully refused to recognize any duty beyond *reporting* suspicious orders. In *Masters Pharmaceutical*, the HDMA, a trade association run by the Distributor Defendants and the NACDS submitted amicus briefs regarding the legal duties of wholesale distributors. Inaccurately denying the legal duties that the wholesale drug industry has been tragically recalcitrant in performing, they argued as follows**:**

a. The Associations complained that the "DEA has required distributors not only to report suspicious orders, but to *investigate* orders (e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled."[238]

b. The Associations argued that, "DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it *is* changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligations on distributors threatens to disrupt patient access to needed prescription medications."[239]

c. The Associations alleged (inaccurately) that nothing "requires distributors to investigate the legitimacy of orders, or to halt shipment of any

[238] Brief for HDMA and NACDS, 2016 WL 1321983, at *4–5.
[239] *Id.* at *8 (citations and quotation marks omitted).

orders deemed to be suspicious."[240]

d. The Association complained that the purported "practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties." [241]

e. The Associations alleged (inaccurately) that "DEA's regulations [] sensibly impose] a duty on distributors simply to *report* suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders." [242]

f. Also inaccurately, the Associations argued that, "[i]mposing a duty on distributors – which lack the patient information and the necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA's demands." [243]

588. The positions taken by the trade groups is emblematic of the position taken by the Distributor Defendants in a disingenuous attempt to deny their legal obligations to prevent diversion of the dangerous drugs.[244]

589. The U.S. Court of Appeals for the District of Columbia has affirmed that a wholesale drug distributor does, in fact, have duties beyond reporting. *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017). Upholding the revocation of Masters Pharmaceutical Inc.'s license, the Court explained that DEA regulations require that in addition to reporting suspicious orders, distributors must "decline to ship the order, or conduct some 'due

[240] *Id.* at *14.
[241] *Id.* at *22.
[242] *Id.* at *24-25.
[243] *Id.* at *26.
[244] *See* Brief of HDMA, 2012 WL 1637016, at *3 (arguing the wholesale distributor industry "does not know the rules of the road because" they claim (inaccurately) that the "DEA has not adequately explained them").

diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order." *Id*. at 212. Master Pharmaceutical Inc. was in violation of its legal duties because it failed to conduct necessary investigations and filled suspicious orders. *Id.* at 218–19, 226. A distributor's investigation must dispel all the red flags giving rise to suspicious circumstance prior to shipping a suspicious order. *Id*. at 226. Notably, the Court rejected HDMA's and NACDS's argument that the DEA had somehow created or imposed new duties. *Id*. at 220.

590. Defendant McKesson was recently forced to admit to specific breaches of its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement entered into between McKesson and the DEA in January 2017 ("2017 McKesson Agreement"), McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."[245]

591. Further, the 2017 McKesson Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a)."[246]

[245] *See* Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp. (Jan. 17, 2017), https://www.justice.gov/opa/press-release/file/928476/download.
[246] *Id.* at 4.

592. McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq*., at the McKesson Distribution Centers," including the McKesson Distribution Center located in Delran, New Jersey."[247]

593. Due to these violations, McKesson agreed that its authority to distribute controlled substances from the New Jersey facility, among other facilities, would be partially suspended.[248]

594. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

595. The 2017 McKesson Agreement followed a 2008 Settlement Agreement in which McKesson also admitted failure to report suspicious orders of controlled substances to the DEA.[249] In the 2008 Settlement Agreement, McKesson "recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA," but had failed to do so. [250] The 2017 McKesson Agreement documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations."[251] As a result of these

[247] *Id*.
[248] *Id*. at 6.
[249] *Id*. at 4.
[250] *Id*.
[251] *Id*.; *see also* Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017) [hereinafter 2017 Settlement Agreement and Release] ("McKesson acknowledges that, at various times during the

violations, McKesson was fined and required to pay to the United States $150,000,000.[252]

596. Because of the Distributor Defendants' refusal to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example, in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.[253] The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.[254]

These actions include the following:

a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain

Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA."), https://www.justice.gov/opa/press-release/file/928471/download.

[252] *See* 2017 Settlement Agreement and Release, at 6.

[253] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

[254] *Id.*

effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that

Cardinal Health failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Lakeland Facility for failure to maintain effective controls against diversion of oxycodone;

i. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against the Lakeland Facility; and

j. On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a $150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora, CO; Aurora, IL; Delran, NJ; LaCrosse, WI; Lakeland, FL; Landover, MD; La Vista, NE; Livonia, MI; Methuen, MA; Santa Fe Springs, CA; Washington Courthouse, OH; and West Sacramento, CA.

597. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's

license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.[255]

598. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

599. For example, a Cardinal Health executive claimed in 2016 that the company used "advanced analytics" to monitor its supply chain, and represented that it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[256] Given the sales volumes and the company's history of violations, this executive was either not telling the truth, or, if Cardinal Health had such a system, it ignored the results.

600. Two months later, Defendant McKesson publicly claimed it had heavily invested in a "best-in-class controlled substance monitoring program to help identify suspicious orders," and that it is "deeply passionate about curbing the opioid epidemic in our country."[257] Again,

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[255] *See* Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowedenforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcementslowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had No Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-.

[256] Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job,"* Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/how-drugs-intendedfor-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html.

[257] Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016, https://www.washingtonpost.com/investigations/key-officials-switch-sides-fromdea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html.

given McKesson's historical conduct, this statement is either false, or the company ignored outputs of the monitoring program.

601. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that the Plaintiff now asserts. The Plaintiff did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

602. Meanwhile, the opioid epidemic rages unabated in the Nation, the State, and in Allentown.

603. The epidemic still rages because the fines and suspensions imposed by the government do not change the overall conduct of the industry. The distributors, including the Distributor Defendants, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

604. The Distributor Defendants have abandoned their duties imposed under federal and state law, taken advantage of a lack of DEA law enforcement, and abused the privilege of distributing controlled substances in the State and Plaintiff's Community.

B. The Marketing Conspirators' Unlawful Failure to Prevent Diversion and Monitor, Report, and Prevent Suspicious Orders

605. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids that were incumbent upon the Distributor Defendants (as detailed above), also were legally required of the Marketing Conspirators under federal and Pennsylvania law, including the public safety statutes discussed above. The Marketing Conspirators were required to comply with the same federal and state licensing and permitting

requirements as the Distributor Defendants. For the Marketing Conspirators, registration with the DEA required, *inter alia*, the:

> maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes . . . .

21 USCA § 823(a)(1).

606. Additionally, as "registrants" with the DEA, the Marketing Conspirators were also required by law to monitor, report, and prevent suspicious orders of controlled substances:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

21 C.F.R. § 1301.74. *See also* 21 C.F.R. § 1301.02 ("Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter."); 21 C.F.R. § 1300.01 ("Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958)." Like the Distributor Defendants, the Marketing Conspirators breached these duties.

607. To be clear, the Marketing Conspirators had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. But perversely, rather than use this information to prevent opioid diversion (as they were required to do), they used this information to sell even more opioids.

608. The Marketing Conspirators engaged in an industry-wide practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product.

609. As reported in *The Washington Post*, identified by U.S. Senator Claire McCaskill, and acknowledged by the HDA, there is an industry-wide practice whereby the manufacturers paid the distributors rebates and/or chargebacks on their prescription opioid sales.[258] Upon information and belief, these contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Marketing Conspirators and Distributor Defendants. In return for the rebates and chargebacks, the Distributor Defendants provided the Marketing Conspirators with detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices. The Marketing Conspirators used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

610. While highly profitable, this practice of chargebacks and rebates was blatantly illegal. Federal statutes and regulations – and Pennsylvania law incorporating those requirements - are clear: just like opioid distributors, opioid manufacturers are required to "design and operate a system to disclose . . . suspicious orders of controlled substances" and to maintain "effective

[258] *See e.g.* Lenny Bernstein & Scott Higham, *The government's struggle to hold opioid manufacturers accountable*, *The Washington Post*, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/deamallinckrodt/?utm_term=.b24cc81cc356.

controls against diversion." 35 Pa.C.S.A. § 780-112(c) via 21 C.F.R. § 1301.74; 21 USCA § 823(a)(1).

611. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law upon opioid manufacturers, fining Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements. In the press release accompanying the settlement, the Department of Justice stated that Mallinckrodt:

> did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone in Florida and elsewhere . . . . Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . . Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands. . . .[259]

612. The settlement resolved, *inter alia*, the government's allegations that "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances – orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders." [260]

613. Mallinckrodt entered into a Memorandum of Agreement ("2017 Mallinckrodt MOA") which acknowledges that "[a]s a registrant under the CSA, Mallinckrodt had a

[259] *See* Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders

[260] *Id.*

responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."[261]

614. The 2017 Mallinckrodt MOA further details the DEA's allegations regarding Mallinckrodt's failures to fulfill its legal duties as an opioid manufacturer:

> With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to:
>
> i. conduct adequate due diligence of its customers;
>
> ii. detect and report to the DEA orders of unusual size and frequency
>
> iii. detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:
>
> 1. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,
>
> 2. orders that purchased a disproportionate amount of a substance which is most often abused compared to other products, and
>
> 3. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;
>
> iv. use "charge back" information from its distributors to evaluate suspicious orders. Chargebacks include

[261] Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC (July 10, 2017), https://www.justice.gov/usao-edmi/press-release/file/986026/download. ("2017 Mallinckrodt MOA").

downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and

v. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.[262]

615. Mallinckrodt agreed that its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007." Mallinckrodt further agreed that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and would "design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product. Further, Mallinckrodt agrees to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."[263]

616. Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to "downstream" registrants." Mallinckrodt agreed that, from this data, it would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion."[264]

617. The same duties imposed by federal law on Mallinckrodt were imposed upon all Marketing Conspirators. Upon information and belief, the same business practices utilized by

[262] 2017 Mallinckrodt MOA at p. 2-3.
[263] *Id.* at 3-4.
[264] *Id.* at p.5.

Mallinckrodt regarding "chargebacks" and receipt and review of data from opioid distributors regarding orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including the other Marketing Conspirators.

618. The Marketing Conspirators failed to monitor, report, and halt suspicious orders of opioids as required by federal law even though they could do so with the assistance of chargeback data and other means.

619. The Marketing Conspirators' failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful.

620. Upon information and belief, the Marketing Conspirators, like the Distributor Defendants, were aware of their duties to the public but breached them anyway. Indeed, the aforementioned letters that the DEA sent to the Distributor Defendants in 2006 and 2007 were also sent to each of the Marketing Conspirators in those years.

621. The Marketing Conspirators have misrepresented their compliance with federal law, and by extension, Pennsylvania law.

622. The Marketing Conspirators enabled the supply of prescription opioids to obviously suspicious physicians and pharmacies, enabled the illegal diversion of opioids, aided criminal activity, and disseminated massive quantities of prescription opioids into the black market.

623. The actions and omissions by Purdue, Cephalon, Endo, Actavis, and Mallinckrodt in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids into Plaintiff's Community.

C. The Defendants Conspired to Increase Revenue, Sales and Profits by Failing to Guard Against Unlawful Diversion

624. The Marketing Conspirators and Distributor Defendants have not undertaken the

practices described herein in isolation, but as part of a common scheme and conspiracy. Collectively breaching their respective statutory duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market, Defendants acted in concert to maximize profit, minimize government interference, and increase sales of prescription opioids.

625. Defendants utilized their interpersonal relationships and communication network to further their goals through contractual relationships, information-sharing, and other coordinated activities. For example, as detailed above, the Marketing Conspirators and Distributor Defendants worked together using chargeback data to sell more opioids instead of prevent their diversion.

626. The Defendants also worked together through vault security programs to further their goals. Each of the defendants is required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opioids. Upon information and belief, Defendants negotiated agreements whereby Marketing Conspirators installed security vaults for Distributor Defendants in exchange for agreements to maintain minimum sales performance thresholds. Upon information and belief, these agreements used by Defendants as a tool to violate their reporting and diversion duties in order to sell more opioids.[265]

627. Finally, Defendants furthered their goals through joint participation in lobbying groups and trade industry organizations, including the Pain Care Forum and the HDA (formerly the HDMA).

[265] Distributor Defendants also developed "know your customer" questionnaires and files that, upon information and belief, were used to provide other Defendants with information that helped them sell more opioids. This information included: the number of pills that certain pharmacies sold; how many noncontrolled substances were sold compared to controlled substances; whether the pharmacy buys from other distributors, and; the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, and cancer treatment facilities. These questionnaires would have also put the recipients on notice of suspicious orders.

628. The Pain Care Forum ("PCF") is a coalition of drugmakers, trade groups and dozens of non-profit organizations supported by industry funding. The PCF shaped public policy regarding the use of prescription opioids for more than a decade.

629. The Center for Public Integrity and The Associated Press obtained "internal documents shed[ding] new light on how drugmakers and their allies shaped the national response to the ongoing wave of prescription opioid abuse."[266] Specifically, PCF members spent over $740 million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including making it more difficult for the DEA to stop suspicious orders of opioids.[267]

630. All of the Defendants stood to profit from lobbying in favor of prescription opioid use. It is not surprising, therefore, that they have all been members and/or participants in the PCF, which has been lobbying on behalf of all of the Defendants for more than a decade.[268] In 2012, the PCF's membership and participating organizations included the HDA (of which all Defendants are members), Endo, Purdue, Johnson & Johnson (the parent company for Janssen Pharmaceuticals), and Teva (the parent company of Cephalon).[269] Through the PCF, the Marketing Conspirators worked with one another as well with the Distributor Defendants (including through their trade organization, the HDA).[270]

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[266] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policyamid-drug-epidemic.

[267] *Id.* at p.5.

[268] *See, e.g.*, PAIN CARE FORUM, 2012 Meetings Schedule, Pain Care Forum (December 2011), https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf.

[269] *Id.* Plaintiff is informed and believes that Mallinckrodt became an active member of the PCF sometime after 2012.

[270] *Id*. The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc., the Executive Vice President and Group President for AmerisourceBergen Corporation,and the President, Pharmaceutical Solutions & Services for McKesson Corporation. Executive Committee,Healthcare Distribution Alliance (accessed on August 13, 2019), https://www.healthcaredistribution.org/about/executive-committee.

631. To achieve their common purpose of violating state and federal requirements to protect against diversion in order to ensure the continued unlawful sale of opioids, Defendants took numerous steps, including but not limited to the following:

a. The Distributor Defendants and the Marketing Conspirators collaborated in their lobbying efforts through the PCF;

b. The Distributor Defendants provided sales information to the Marketing Conspirators regarding their prescription opioids, including reports of all opioids prescriptions filled by the Distributor Defendants;

c. The Marketing Conspirators used a chargeback program to ensure delivery of the Distributor Defendants' sales information;

d. The Marketing Conspirators used sales information showing how individual prescribers across the nation were prescribing opioids.

e. The Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;

f. The Marketing Conspirators used the Distributor Defendants' sales information and the data to instruct the Distributor Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent;

g. Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market; and

h. Defendants withheld information regarding suspicious orders and illicit diversion from federal and state authorities; and

i. Defendants made false statements to authorities, the public, and others regarding their compliance with federal and state law to maintain controls against diversion.

X. Facts Pertaining to Claims Under the Racketeer-Influenced and Corrupt Organizations Act ("RICO")

A. The Opioid Marketing Enterprise

1. The Common Purpose and Scheme of the Opioid Marketing Enterprise

632. Knowing that their products were highly addictive, ineffective and unsafe for the treatment of long-term chronic pain, non-acute and non-cancer pain, the RICO Marketing Defendants[271] and Janssen formed an association-in-fact enterprise and engaged in a scheme to unlawfully increase their profits and sales, and grow their share of the prescription painkiller market, through repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term chronic pain.

633. In order to unlawfully increase the demand for opioids, the RICO Marketing Defendants and Janssen formed an association-in-fact enterprise (the "Opioid Marketing Enterprise") with the "Front Groups" and KOLs described above. Through their personal relationships, the members of the Opioid Marketing Enterprise had the opportunity to form and take actions in furtherance of the Opioid Marketing Enterprise's common purpose. The RICO Marketing Defendants' (and Janssen's) substantial financial contribution to the Opioid Marketing Enterprise, and the advancement of opioid-friendly messaging, fueled the U.S. opioid epidemic.

634. The RICO Marketing Defendants and Janssen, through the Opioid Marketing

[271] The RICO Marketing Defendants referred to in this section are those named in the claims for relief in Count I: Purdue; Cephalon; Endo, and; Mallinckrodt.

Enterprise, concealed the true risks and dangers of opioids from the medical community and the public, including Plaintiff, and made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use. The misleading statements included: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition the RICO Marketing Defendants and Janssen named "pseudoaddiction"; (4) that withdrawal is easily managed; (5) that increased dosing presents no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

635. The scheme devised, implemented and conducted by the RICO Marketing Defendants and Janssen was a common course of conduct designed to ensure that the RICO Marketing Defendants and Janssen unlawfully increased their sales and profits through concealment and misrepresentations about the addictive nature and effective use of the RICO Marketing Defendants' (and Janssen's) drugs. The RICO Marketing Defendants, Janssen, the Front Groups, and the KOLs acted together for a common purpose and perpetuated the Opioid Marketing Enterprise's scheme, including through the unbranded promotion and marketing network as described above.

636. There was regular communication between the RICO Marketing Defendants, Janssen, Front Groups and KOLs, in which information was shared, misrepresentations were coordinated, and payments were exchanged. Typically, the coordination, communication and payment occurred, and continues to occur, through the repeated and continuing use of the wires

and mail in which the RICO Marketing Defendants, Janssen, Front Groups, and KOLs share information regarding overcoming objections and resistance to the use of opioids for chronic pain. The RICO Marketing Defendants, Janssen, Front Groups and KOLs functioned as a continuing unit for the purpose of implementing the Opioid Marketing Enterprise's scheme and common purpose, and each agreed and took actions to hide the scheme and continue its existence.

637. At all relevant times, the Front Groups were aware of the RICO Marketing Defendants's (and Janssen's) conduct, were knowing and willing participants in and beneficiaries of that conduct. Each Front Group also knew, but did not disclose, that the other Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and Plaintiff. But for the Opioid Marketing Enterprise's unlawful fraud, the Front Groups would have had incentive to disclose the deceit by the RICO Marketing Defendants, Janssen, and the Opioid Marketing Enterprise to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Opioid Marketing Enterprise's scheme and common purpose, and reaped substantial benefits.

638. At all relevant times, the KOLs were aware of the RICO Marketing Defendants's (and Janssen's) conduct, were knowing and willing participants in that conduct, and reaped benefits from that conduct. The RICO Marketing Defendants and Janssen selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids. The RICO Marketing Defendants's (and Janssen's) support helped the KOLs become respected industry experts. And, as they rose to prominence, the KOLs falsely touted the benefits of using opioids to treat chronic pain, repaying the RICO Marketing Defendants and Janssen by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLS and Front

Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and Plaintiff. But for the Opioid Marketing Enterprise's unlawful conduct, the KOLs would have had incentive to disclose the deceit by the RICO Marketing Defendants, Janssen and the Opioid Marketing Enterprise, and to protect their patients and the patients of other physicians. By failing to disclose this information, KOLs furthered the Opioid Marketing Enterprise's scheme and common purpose, and reaped substantial benefits.

639. As public scrutiny and media coverage focused on how opioids ravaged communities in Pennsylvania and throughout the United States, the Front Groups and KOLs did not challenge the RICO Marketing Defendants's (and Janssen's) misrepresentations, seek to correct their previous misrepresentations, terminate their role in the Opioid Marketing Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits and were not supported by medically acceptable evidence.

640. The RICO Marketing Defendants, Janssen, Front Groups and KOLs engaged in certain discrete categories of activities in furtherance of the common purpose of the Opioid Marketing Enterprise. As described herein, the Opioid Marketing Enterprise's conduct in furtherance of the common purpose of the Opioid Marketing Enterprise involved: (1) misrepresentations regarding the risk of addiction and safe use of prescription opioids for long-term chronic pain (described in detail above); (2) lobbying to defeat measures to restrict over-prescription; (3) efforts to criticize or undermine CDC guidelines; and (4) efforts to limit prescriber accountability.

641. In addition to disseminating misrepresentations about the risks and benefits of opioids, the Opioid Marketing Enterprise also furthered its common purpose by criticizing or undermining CDC Guidelines. Members of the Opioid Marketing Enterprise criticized or

undermined the CDC Guidelines, which represented "an important step—and perhaps the first major step from the federal government—toward limiting opioid prescriptions for chronic pain."

642. Several Front Groups, including the U.S. Pain Foundation and the AAPM, criticized the draft guidelines in 2015, arguing that the "CDC slides presented on Wednesday were not transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest of the individuals who participated in the construction of these guidelines."

643. The AAPM criticized the prescribing guidelines in 2016, through its immediate past president, stating "that the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence."

644. The RICO Marketing Defendants and Janssen alone could not have accomplished the purpose of the Opioid Marketing Enterprise without the assistance of the Front Groups and KOLs, who were perceived as "neutral" and more "scientific" than the RICO Marketing Defendants and Janssen themselves. Without the work of the Front Groups and KOLs in spreading misrepresentations about opioids, the Opioid Marketing Enterprise could not have achieved its common purpose.

645. The impact of the Opioid Marketing Enterprise's scheme is still felt—*i.e.*, the opioids continue to be prescribed and used for chronic pain throughout the area of Allentown and the epidemic continues to injure Plaintiff and consume the resources of Plaintiff's health care and law enforcement systems.

646. As a result, it is clear that the RICO Marketing Defendants, Janssen, the Front Groups, and the KOLs were each willing participants in the Opioid Marketing Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure

designed to effectuate the Enterprise's purpose.

2. The Conduct of the Opioid Marketing Enterprise Violated Civil RICO

647. From approximately the late 1990s to the present, each of the RICO Marketing Defendants and Janssen exerted control over the Opioid Marketing Enterprise and participated in the operation or management of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. Creating and providing a body of deceptive, misleading and unsupported medical and popular literature about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

b. Creating and providing a body of deceptive, misleading and unsupported electronic and print advertisements about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

c. Creating and providing a body of deceptive, misleading and unsupported sales and promotional training materials about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

d. Creating and providing a body of deceptive, misleading and unsupported CMEs and speaker presentations about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

e. Selecting, cultivating, promoting and paying KOLs based solely on their willingness to communicate and distribute the RICO Marketing Defendants's (and Janssen's) messages about the use of opioids for chronic pain;

f. Providing substantial opportunities for KOLs to participate in research studies on topics the RICO Marketing Defendants and Janssen suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

g. Paying KOLs to serve as consultants or on the RICO Marketing Defendants's (and Janssen's) advisory boards, on the advisory boards and in leadership positions in Front Groups, and to give talks or present CMEs, typically over

meals or at conferences;

h. Selecting, cultivating, promoting, creating and paying Front Groups based on their willingness to communicate and distribute the RICO Marketing Defendants's (and Janssen's) messages about the use of opioids for chronic pain;

i. Providing substantial opportunities for Front Groups to participate in and/or publish research studies on topics the RICO Marketing Defendants and Janssen suggested or chose (and paid for), with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

j. Paying significant amounts of money to the leaders and individuals associated with Front Groups;

k. Donating to Front Groups to support talks or CMEs, that were typically presented over meals or at conferences;

l. Disseminating many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;

m. Sponsoring CME programs put on by Front Groups that focused on the use of opioids for chronic pain;

n. Developing and disseminating pro-opioid treatment guidelines with the help of the KOLs as authors and promoters, and the help of the Front Groups as publishers, and supporters;

o. Encouraging Front Groups to disseminate their pro-opioid messages to groups targeted by the RICO Marketing Defendants and Janssen, such as veterans and the elderly, and then funding that distribution;

p. Concealing their relationship to and control of Front Groups and KOLs from Plaintiff and the public at large; and

q. Intending that Front Groups and KOLs would distribute through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain.

648. The Opioid Marketing Enterprise had a hierarchical decision-making structure that was headed by the RICO Marketing Defendants and Janssen in coordination with the KOLs and Front Groups. The RICO Marketing Defendants and Janssen controlled representations made about their opioids and their drugs, doled out funds to PBMs and payments to KOLs, and ensured that representations made by KOLs, Front Groups, and the RICO Marketing Defendants's (and Janssen's) sales detailers were consistent with the Marketing Conspriators' messaging throughout the United States and Pennsylvania. The Front Groups and KOLs in the

Opioid Marketing Enterprise were dependent on the RICO Marketing Defendants and Janssen for their financial structure and for career development and promotion opportunities.

649. The Front Groups also conducted and participated in the conduct of the Opioid Marketing Enterprise, directly or indirectly, in the following ways: from approximately the late 1990s to the present, each of the RICO Marketing Defendants and Janssen exerted control over the Opioid Marketing Enterprise and participated in the operation or management of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. The Front Groups promised to, and did, make representations regarding opioids and the RICO Marketing Defendants's (and Janssen's) drugs that were consistent with the RICO Marketing Defendants's (and Janssen's) messages;

b. The Front Groups distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented that the benefits of using opioids for chronic pain outweighed the risks;

c. The Front Groups echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the RICO Marketing Defendants;

d. The Front Groups issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

e. The Front Groups strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and

f. The Front Groups concealed their connections to the KOLs and the RICO Marketing Defendants and Janssen.

650. The RICO Marketing Defendants's (and Janssen's) Front Groups, "with their large numbers and credibility with policymakers and the public—have 'extensive influence in specific disease areas.'" The larger Front Groups "likely have a substantial effect on policies relevant to their industry sponsors." [272] "By aligning medical culture with industry goals in this

[272] *Fueling an Epidemic*, *supra* note 154, at 1.

way, many of the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioid epidemic."[273]

651. The KOLs also participated in the conduct of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. The KOLs promised to, and did, make representations regarding opioids and the RICO Marketing Defendants's (and Janssen's) drugs that were consistent with the RICO Marketing Defendants's (and Janssen's) messages themselves;

b. The KOLs distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented that the benefits of using opioids for chronic pain outweighed the risks;

c. The KOLs echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the RICO Marketing Defendants;

d. The KOLs issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

e. The KOLs strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and

f. The KOLs concealed their connections to the Front Groups, Janssen, and the RICO Marketing Defendants, and their sponsorship by the RICO Marketing Defendants and Janssen.

652. The scheme devised and implemented by the RICO Marketing Defendants, Janssen and members of the Opioid Marketing Enterprise, amounted to a common course of conduct intended to increase the RICO Marketing Defendants's (and Janssen's) sales from prescription opioids by encouraging the prescribing and use of opioids for long-term chronic pain. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

[273] *Id. at 2.*

3. The RICO Marketing Defendants Controlled and Paid Front Groups and KOLs to Promote and Maximize Opioid Use

653. As discussed in detail above, the RICO Marketing Defendants and Janssen funded and controlled the various Front Groups, including APF, AAPM/APS, FSMB, Alliance for Patient Access, USPF, and AGS. The Front Groups, which appeared to be independent, but were not, transmitted the RICO Marketing Defendants's (and Janssen's) misrepresentations. The RICO Marketing Defendants, Janssen and the Front Groups thus worked together to promote the goals of the Opioid Marketing Enterprise.

654. The RICO Marketing Defendants and Janssen worked together with each other through the Front Groups that they jointly funded and through which they collaborated on the joint promotional materials described above.

655. Similarly, as discussed in detail above, the RICO Marketing Defendants and Janssen paid KOLs, including Drs. Portenoy, Fine, Fishman, and Webster, to spread their misrepresentations and promote their products. The RICO Marketing Defendants, Janssen and the KOLs thus worked together to promote the goals of the Opioid Marketing Enterprise.

4. Pattern of Racketeering Activity

656. The RICO Marketing Defendants's (and Janssen's) scheme described herein was perpetrated, in part, through multiple acts of mail fraud and wire fraud, constituting a pattern of racketeering activity as described herein.

657. The pattern of racketeering activity used by the RICO Marketing Defendants, Janssen and the Opioid Marketing Enterprise likely involved thousands of separate instances of the use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Opioid Marketing Enterprise, including essentially uniform misrepresentations, concealments and

material omissions regarding the beneficial uses and non-addictive qualities for the long-term treatment of chronic, non-acute and non-cancer pain, with the goal of profiting from increased sales of the RICO Marketing Defendants's (and Janssen's) drugs induced by consumers, prescribers, regulators and Plaintiff's reliance on the RICO Marketing Defendants's (and Janssen's) misrepresentations.

658. Each of these fraudulent mailings and interstate wire transmissions constitutes racketeering activity and collectively, these violations constitute a pattern of racketeering activity, through which the RICO Marketing Defendants, Janssen, the Front Groups and the KOLs defrauded and intended to defraud Pennsylvania consumers, the State, and other intended victims.

659. The RICO Marketing Defendants and Janssen devised and knowingly carried out an illegal scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts regarding the safe, non-addictive and effective use of opioids for long-term chronic, non-acute and non-cancer pain. The RICO Marketing Defendants, Janssen, and members of the Opioid Marketing Enterprise knew that these representations violated the FDA approved use these drugs, and were not supported by actual evidence. The RICO Marketing Defendants and Janssen intended that that their common purpose and scheme to defraud would, and did, use the U.S. Mail and interstate wire facilities, intentionally and knowingly with the specific intent to advance, and for the purpose of executing, their illegal scheme.

660. By intentionally concealing the material risks and affirmatively misrepresenting the benefits of using opioids for chronic pain to prescribers, regulators and the public, including Plaintiff, the RICO Marketing Defendants, Janssen, the Front Groups and the KOLs engaged in a

fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

661. The RICO Marketing Defendants's (and Janssen's) use of the U.S. Mail and interstate wire facilities to perpetrate the opioids marketing scheme involved thousands of communications, publications, representations, statements, electronic transmissions, payments, including, *inter alia*:

a. Marketing materials about opioids, and their risks and benefits, which the RICO Marketing Defendants and Janssen sent to health care providers, transmitted through the internet and television, published, and transmitted to Front Groups and KOLs located across the country and Plaintiff's community;

b. Written representations and telephone calls between the RICO Marketing Defendants, Janssen, and Front Groups regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;

c. Written representations and telephone calls between the RICO Marketing Defendants, Janssen, and KOLs regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;

d. E-mails, telephone and written communications between the RICO Marketing Defendants, Janssen, and the Front Groups agreeing to or implementing the opioids marketing scheme;

e. E-mails, telephone and written communications between the RICO Marketing Defendants, Janssen, and the KOLs agreeing to or implementing the opioids marketing scheme;

f. Communications between the RICO Marketing Defendants, Janssen, Front Groups and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;

g. Communications between the RICO Marketing Defendants, Janssen, KOLs and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;

h. Written and oral communications directed to State agencies, federal and state courts, and private insurers throughout the Plaintiff's communities that fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and

i. Receipts of increased profits sent through the U.S. Mail and interstate wire facilities—the wrongful proceeds of the scheme.

662. In addition to the above-referenced predicate acts, it was intended by and foreseeable to the RICO Marketing Defendants and Janssen that the Front Groups and the KOLs would distribute publications through the U.S. Mail and by interstate wire facilities, and, in those publications, claim that the benefits of using opioids for chronic pain outweighed the risks of doing so.

663. To achieve the common goal and purpose of the Opioid Marketing Enterprise, the RICO Marketing Defendants, Janssen, and members of the Opioid Marketing Enterprise hid from the consumers, prescribers, regulators and Plaintiff: (a) the fraudulent nature of the RICO Marketing Defendants's (and Janssen's) marketing scheme; (b) the fraudulent nature of statements made by the RICO Marketing Defendants and Janssen and by their KOLs, Front Groups and other third parties regarding the safety and efficacy of prescription opioids; and (c) the true nature of the relationship between the members of the Opioid Marketing Enterprise.

664. The RICO Marketing Defendants, Janssen, and each member of the Opioid Marketing Enterprise agreed, with knowledge and intent, to the overall objective of the RICO Marketing Defendants's (and Janssen's) fraudulent scheme and participated in a common course of conduct to commit acts of fraud and deception in marketing prescription opioids.

665. Indeed, for the RICO Marketing Defendants's (and Janssen's) fraudulent scheme to work, each of them had to agree to implement similar tactics regarding fraudulent marketing of prescription opioids. This conclusion is supported by the fact that the RICO Marketing Defendants and Janssen each financed, supported, and worked through the same KOLs and Front Groups, and often collaborated on and mutually supported the same publications, CMEs, presentations, and prescription guidelines.

666. The RICO Marketing Defendants's (and Janssen's) predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiff's business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Marketing Defendants and Janssen. The predicate acts were committed or caused to be committed by the RICO Marketing Defendants through their participation in the Opioid Marketing Enterprise and in furtherance of its fraudulent scheme.

B. The Opioid Supply Chain Enterprise

667. Faced with the reality that they will now be held accountable for the consequences of the opioid epidemic they created, members of the industry resort to, as McKesson articulated in response to a 60 Minutes story about its 2017 settlement with the federal government, "a categorical denial of any criminal behavior or intent." Defendants' actions went far beyond what could be considered ordinary business conduct. For more than a decade, certain Defendants, the "RICO Supply Chain Defendants" (Purdue, Cephalon, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, and AmerisourceBergen) worked together in an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-competitive, with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding a market that the law intended to restrict.

668. Knowing that dangerous drugs have a limited place in our society, and that their dissemination and use must be vigilantly monitored and policed to prevent the harm that drug abuse and addiction causes to individuals, society and governments, Congress enacted the Controlled Substances Act ("CSA"). Specifically, through the CSA, which created a closed system of distribution for controlled substances, Congress established an enterprise for the public good. CSA imposes a reporting duty that cuts across company lines. Regulations adopted under

the CSA require that companies who are entrusted with permission to operate within this system cannot simply operate as competitive in an "anything goes" profit-maximizing market. Instead, the statute tasks them to watch over each other with a careful eye for suspicious activity. Driven by greed, Defendants betrayed that trust and subverted the constraints of the CSA's closed system to conduct their own enterprise for profit.

669. As "registrants" under the CSA, the RICO Supply Chain Defendants are duty bound to identify and report "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[274] Critically, these Defendants' responsibilities do not end with the products they manufacture or distribute—there is no such limitation in the law because their duties cut across company lines. Thus, when these Defendants obtain information about the sales and distribution of other companies' opioid products, as they did through data mining companies like IMS Health, they were legally obligated to report that activity to the DEA.

670. If morality and the law did not suffice, competition dictates that the RICO Supply Chain Defendants would turn in their rivals when they had reason to suspect suspicious activity. Indeed, if a manufacturer or distributor could gain market share by reporting a competitor's illegal behavior (causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business conduct dictates that it would do so. Under the CSA, this whistleblower or watchdog function is not only a protected choice, but a statutory mandate. Unfortunately, however, that is not what happened. Instead, knowing that investigations into potential diversion would only lead to shrinking markets, the RICO Supply Chain Defendants elected to operate in a conspiracy of silence, in violation of both the CSA and RICO.

[274] 21 C.F.R. § 1301.74(b).

671. The RICO Supply Chain Defendants' scheme required the participation of all. If any one member broke rank, its compliance activities would highlight the deficiencies of the others, and the artificially high quotas they maintained through their scheme would crumble. But, if all the members of the enterprise conducted themselves in the same manner, it would be difficult for the DEA to go after any one of them. Accordingly, through the connections they made as a result of their participation in the Healthcare Distribution Alliance ("HDA"), the RICO Supply Chain Defendants chose to flout the closed system designed to protect the citizens. Publicly, in 2008, they announced their formulation of "Industry Compliance Guidelines: Reporting Suspicious Orders and Prevention Diversion of Controlled Substances." But, privately, the RICO Supply Chain Defendants refused to act and through their lobbying efforts, they collectively sought to undermine the impact of the CSA. Indeed, despite the issuance of these Industry Compliance Guidelines, which recognize these Defendants' duties under the law, as illustrated by the subsequent industry-wide enforcement actions and consent orders issued after that time, none of them complied. John Gray, President and CEO of the HDA said to Congress in 2014, it is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Yet, the RICO Supply Chain Defendants apparently all found the same profit-maximizing balance -- intentionally remaining silent to ensure the largest possible financial return.

672. As described above, at all relevant times, the RICO Supply Chain Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by fraudulently increasing the quotas set by the DEA that would allow them to collectively benefit from a greater pool of prescription opioids to manufacture and distribute. In support of this common purpose and fraudulent scheme, the RICO Supply Chain

Defendants jointly agreed to disregard their statutory duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market so that those orders would not result in a decrease, or prevent an increase in, the necessary quotas.

673. At all relevant times, as described above, the RICO Supply Chain Defendants exerted control over, conducted and/or participated in the Opioid Supply Chain Enterprise by fraudulently claiming that they were complying with their duties under the CSA to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, and to halt such unlawful sales, so as to increase production quotas and generate unlawful profits, as follows.

674. The RICO Supply Chain Defendants disseminated false and misleading statements to state and federal regulators claiming that:

a. the quotas for prescription opioids should be increased;

b. they were complying with their obligations to maintain effective controls against diversion of their prescription opioids;

c. they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids;

d. they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids; and

e. they did not have the capability to identify suspicious orders of controlled substances.

675. The Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."[275]

[275] HDMA is Now the Healthcare Distribution Alliance, Pharmaceutical Commerce, http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution- alliance/ (last updated

676. The CSA and the Code of Federal Regulations require the RICO Supply Chain Defendants to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders. The failure to make reports as required by the CSA and Code of Federal Regulations amounts to a criminal violation of the statute.

677. The RICO Supply Chain Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the DEA including the Marketing Conspirators' applications for production quotas. Specifically, the RICO Supply Chain Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

678. The RICO Supply Chain Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

679. In devising and executing the illegal scheme, the RICO Supply Chain Defendants

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July 6, 2016); Lenny Bernstein & Scott Higham, Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control, Wash. Post (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the- opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis, Wash. Post (Mar. 6, 2017), https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea- enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills, Charleston Gazette-Mail (Feb. 18, 2017), http://www.wvgazettemail.com/news/20170218/dea-agent-we- had-no-leadership-in-wv-amid-flood-of-pain-pills-.

devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

680. For the purpose of executing the illegal scheme, the RICO Supply Chain Defendants committed racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme. These racketeering acts, which included repeated acts of mail fraud and wire fraud, constituted a pattern of racketeering.

681. The RICO Supply Chain Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Marketing Conspirators, the Distributor Defendants, or third parties that were foreseeably caused to be sent as a result of the RICO Supply Chain Defendants' illegal scheme, including but not limited to:

a. The prescription opioids themselves;

b. Documents and communications that supported and/or facilitated the RICO Supply Chain Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;

c. Documents and communications that facilitated the manufacture, purchase and sale of prescription opioids;

d. RICO Supply Chain Defendants' DEA registrations;

e. Documents and communications that supported and/or facilitated RICO Supply Chain Defendants' DEA registrations;

f. RICO Supply Chain Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;

g. Documents and communications related to the RICO Supply Chain Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;

h. Documents intended to facilitate the manufacture and distribution of the RICO Supply Chain Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;

i. Documents for processing and receiving payment for prescription opioids;

j. Payments from the Distributor Defendants to the Marketing Conspirators;

k. Rebates and chargebacks from the Marketing Conspirators to the Distributors Defendants;

l. Payments to the RICO Supply Chain Defendants' lobbyists through the PCF;

m. Payments to the RICO Supply Chain Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

n. Deposits of proceeds from the RICO Supply Chain Defendants' manufacture and distribution of prescription opioids; and

o. Other documents and things, including electronic communications.

682. The RICO Supply Chain Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

Defendant Group Name	**Company Names**	**Drugs**		
		Drug Name	**Chemical Name**	**CSA Schedul**
Purdue	(1) Purdue Pharma, LP, (2) Purdue Pharma, Inc., (3) The Purdue Frederick Company	OxyContin	Oxycodone hydrochloride extended release	Schedule II
		OxyContin	Oxycodone hydrochloride extended release	Schedule II
		MS Contin	Morphine sulfate extended release	Schedule II
		Dilaudid	Hydromorphone hydrochloride	Schedule II
		Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
		Butrans	Buprenorphine	Schedule II
		Hysinga ER	Hydrocodone bitrate	Schedule II

		Targiniq ER	Oxycodone hydrochloride	Schedule II
Cephalon	(1) Cephalon, Inc., (2) Teva Pharmaceutical Industries, Ltd., (3) Teva Pharmaceuticals USA, Inc.	Actiq	Fentanyl citrate	Schedule II
		Fentora	Fentanyl citrate	Schedule II
		Generic oxycodone	Oxycodone hydrochloride	Schedule II
Endo	(1) Endo Health Solutions, Inc., (2) Endo Pharmaceuticals Inc., (3) Qualitest Pharmaceuticals, Inc. (*wholly-owned subsidiary of Endo*)	Opana ER	Oxymorphone hydrochloride extended release	Schedule II
		Opana	Oxymorphone hydrochloride	Schedule II
		Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
		Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II
		Generic oxycodone		Schedule II
		Generic oxymorphone		Schedule II
		Generic hydromorphone		Schedule II
		Generic hydrocodone		Schedule II
Mallinckrodt	(1) Mallinckrodt plc, (2) Mallinckrodt LLC (*wholly-owned subsidiary of Mallinckrodt plc*)	Exalgo	Hydromorphone hydrochloride	Schedule II
		Roxicodone	Oxycodone hydrochloride	Schedule II
Allergan	(1) Allergan Plc, (2) Actavis LLC, (3) Actavis Pharma, Inc., (4) Actavis Plc,	Kadian	Morphine Sulfate	Schedule II
		Norco (Generic of Kadian)	Hydrocodone and acetaminophen	Schedule II
	(5) Actavis, Inc., (6) Watson Pharmaceuticals, Inc.	Generic Duragesic	Fentanyl	Schedule II
		Generic Opana	Oxymorphone hydrochloride	Schedule II

683. Each of the RICO Supply Chain Defendants identified manufactured, shipped, paid for and received payment for the drugs identified above, throughout the United States..

684. The RICO Supply Chain Defendants used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the RICO Supply Chain Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

685. At the same time, the RICO Supply Chain Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and their compliance with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

686. The RICO Supply Chain Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

687. The RICO Supply Chain Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail with each other and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

688. The mail and wire transmissions described herein were made in furtherance of the RICO Supply Chain Defendants' scheme and common course of conduct to deceive regulators, the public and Plaintiff that these Defendants were complying with their state and federal

obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The RICO Supply Chain Defendants' scheme and common course of conduct was to increase or maintain high production quotas for their prescription opioids from which they could profit.

689. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden by Defendants and cannot be alleged without access to Defendants' books and records. However, Plaintiff has described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

690. The RICO Supply Chain Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with these Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the RICO Supply Chain Defendants.

691. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

692. The predicate acts all had the purpose of creating the opioid epidemic that

substantially injured Plaintiff's business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Supply Chain Defendants. The predicate acts were committed or caused to be committed by the Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

693. As described above, the RICO Supply Chain Defendants were repeatedly warned, fined, and found to be in violation of applicable law and regulations, and yet they persisted. The sheer volume of enforcement actions against the RICO Supply Chain Defendants supports this conclusion that the RICO Supply Chain Defendants operated through a pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74.

694. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, Plaintiff's communities and Plaintiff. The RICO Supply Chain Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on this jurisdiction, its citizens or Plaintiff. The RICO Supply Chain Defendants were aware that Plaintiff and the citizens of Allentown rely on these Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

695. By intentionally refusing to report and halt suspicious orders of their prescription opioids, the RICO Supply Chain Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

XI. Claims for Relief

696. As a result of Defendants' fraudulent and unlawful conduct, Plaintiff has suffered significant harm, as discussed above. As set forth herein, Plaintiff seeks monetary damages, including actual damages, compensatory damages, punitive damages and attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

697. As set forth herein, Plaintiff also seeks injunctive relief to enjoin Defendants' improper conduct and abate the nuisance to the fullest extent practicable and appropriate.

COUNT I
RICO, 18 U.S.C. § 1964(c) – Opioid Marketing Enterprise
(Against Purdue, Cephalon, Endo, and Mallinckrodt
(the "RICO Marketing Defendants"))

698. Plaintiff repeats, re-alleges, and incorporates by reference each and every allegation set forth above as if fully set forth herein.

699. The RICO Marketing Defendants—through the use of "Front Groups" that appeared to be independent of the RICO Marketing Defendants; through the dissemination of publications that supported the RICO Marketing Defendants' (and Janssen's) scheme; through continuing medical education ("CME") programs controlled and/or funded by the RICO Marketing Defendants and Janssen; by the hiring and deployment of so-called "key opinion leaders," ("KOLs") who were paid by the RICO Marketing Defendants and Janssen to promote their message; and through the "detailing" activities of the RICO Marketing Defendants' (and Janssen's) sales forces—conducted an association-in-fact enterprise, and/or participated in the conduct of an enterprise through a pattern of illegal activities (the predicate racketeering acts of mail and wire fraud) to carry-out the common purpose of the Opioid Marketing Enterprise, *i.e.*, to unlawfully increase profits and revenues from the continued prescription and use of opioids for long-term chronic pain. Through the racketeering activities of the Opioid Marketing Enterprise the RICO Marketing Defendants sought to further the common purpose of the enterprise through a fraudulent scheme to change prescriber habits and public perception about the safety and efficacy of opioid use by convincing them that each of the nine false propositions alleged earlier were true. In so doing, each of the RICO Marketing Defendants and Janssen knowingly conducted and participated in the conduct of the Opioid Marketing Activities by engaging in mail and wire fraud in violation of 18 U.S.C. §§ 1962(c) and (d).

700. The Opioid Marketing Enterprise alleged above, is an association-in-fact

enterprise that consists of the RICO Marketing Defendants (Purdue, Cephalon, Endo, and Mallinckrodt); the Front Groups (APF, AAPM, APS, FSMB, USPF, and AGS); and the KOLs (including Dr. Portenoy, Dr. Webster, Dr. Fine, and Dr. Fishman).

701. Each of the RICO Marketing Defendants and Janssen and the other members of the Opioid Marketing Enterprise conducted and participated in the conduct of the Opioid Marketing Enterprise by playing a distinct role in furthering the enterprise's common purpose of increasing profits and sales through the knowing and intentional dissemination of false and misleading information about the safety and efficacy of long-term opioid use, and the risks and symptoms of addiction, in order to increase the market for prescription opioids by changing prescriber habits and public perceptions and increasing thereby the market for opioids.

702. Specifically, the RICO Marketing Defendants and Janssen each worked together to coordinate the enterprise's goals and conceal their role, and the enterprise's existence, from the public by, among other things, (i) funding, editing and distributing publications that supported and advanced their false messages; (ii) funding KOLs to further promote their false messages; (iii) funding, editing and distributing CME programs to advance their false messages; and (iv) tasking their own employees to target deceptive marketing materials and pitches directly at physicians and, in particular, at physicians lacking the expertise of pain care specialists (a practice known as sales detailing).

703. Each of the Front Groups helped disguise the role of RICO Marketing Defendants and Janssen by purporting to be unbiased, independent patient-advocacy and professional organizations in order to disseminate patient education materials, a body of biased and unsupported scientific "literature," and "treatment guidelines" that promoted the RICO Marketing Defendants's and Janssen's false messages.

704. Each of the KOLs were physicians chosen and paid by each of the RICO Marketing Defendants and Janssen to influence their peers' medical practice by promoting the Marketing Conspirators' false message through, among other things, writing favorable journal articles and delivering supportive CMEs as if they were independent medical professionals, thereby further obscuring the RICO Marketing Defendants' (and Janssen's) role in the enterprise and the enterprise's existence.

705. Further, each of the RICO Marketing Defendants, Janssen, KOLs and Front Groups that made-up the Opioid Marketing Enterprise had systematic links to and personal relationships with each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. The systematic links and personal relationships that were formed and developed allowed members of the Opioid Marketing Enterprise the opportunity to form the common purpose and agree to conduct and participate in the conduct of the Opioid Marketing Enterprise. Specifically, each of the RICO Marketing Defendants and Janssen coordinated their efforts through the same KOLs and Front Groups, based on their agreement and understanding that the Front Groups and KOLs were industry friendly and would work together with the RICO Marketing Defendants and Janssen to advance the common purpose of the Opioid Marketing Enterprise; each of the individuals and entities who formed the Opioid Marketing Enterprise acted to enable the common purpose and fraudulent scheme of the Opioid Marketing Enterprise.

706. At all relevant times, the Opioid Marketing Enterprise: (a) had an existence separate and distinct from each RICO Marketing Defendant and its members; (b) was separate and distinct from the pattern of racketeering in which the RICO Marketing Defendants and Janssen engaged; (c) was an ongoing and continuing organization consisting of individuals,

persons, and legal entities, including each of the RICO Marketing Defendants; (d) was characterized by interpersonal relationships between and among each member of the Opioid Marketing Enterprise, including between the RICO Marketing Defendants and Janssen and each of the Front Groups and KOLs; (e) had sufficient longevity for the enterprise to pursue its purpose and functioned as a continuing unit.

707. The persons and entities engaged in the Opioid Marketing Enterprise are systematically linked through contractual relationships, financial ties, personal relationships, and continuing coordination of activities, as spearheaded by the RICO Marketing Defendants and Janssen.

708. The RICO Marketing Defendants conducted and participated in the conduct of the Opioid Marketing Enterprise through a pattern of racketeering activity that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud), to increase profits and revenue by changing prescriber habits and public perceptions in order to increase the prescription and use of prescription opioids, and expand the market for opioids.

709. The RICO Marketing Defendants each committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.* violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Marketing Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Marketing Defendants's (and Janssen's) regular use of the facilities, services, distribution channels, and employees of the Opioid Marketing Enterprise, the U.S. Mail and interstate wire facilities. The RICO Marketing Defendants participated in the scheme to

defraud by using mail, telephones and the Internet to transmit mailings and wires in interstate or foreign commerce.

710. The RICO Marketing Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a. Mail Fraud: The RICO Marketing Defendants and Janssen violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

b. Wire Fraud: The RICO Marketing Defendants and Janssen violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

711. Indeed, as summarized herein, the RICO Marketing Defendants and Janssen used the mail and wires to send or receive thousands of communications, publications, representations, statements, electronic transmissions and payments to carry-out the Opioid Marketing Enterprise's fraudulent scheme.

712. Because the RICO Marketing Defendants and Janssen disguised their participation in the enterprise, and worked to keep even the enterprise's existence secret so as to give the false appearance that their false messages reflected the views of independent third parties, many of the precise dates of the Opioid Marketing Enterprise's uses of the U.S. Mail and interstate wire facilities (and corresponding predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to the books and records maintained by the RICO Marketing Defendants, Janssen, Front Groups, and KOLs. Indeed, an essential part of the successful operation of the Opioid Marketing Enterprise alleged herein depended upon secrecy. However, Plaintiff has described the occasions on which the RICO Marketing Defendants,

Janssen, Front Groups, and KOLs disseminated misrepresentations and false statements to Pennsylvania consumers, prescribers, regulators and Plaintiff, and how those acts were in furtherance of the scheme.

713. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Pennsylvania consumers, prescribers, regulators and Plaintiff. The RICO Marketing Defendants, Janssen, Front Groups and KOLs calculated and intentionally crafted the scheme and common purpose of the Opioid Marketing Enterprise to ensure that their own profits remained high. In designing and implementing the scheme, the RICO Marketing Defendants and Janssen understood and intended that those in the distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and scientific evidence regarding the RICO Marketing Defendants's (and Janssen's) products.

714. The RICO Marketing Defendants' (and Janssen's) pattern of racketeering activity alleged herein and the Opioid Marketing Enterprise are separate and distinct from each other. Likewise, the RICO Marketing Defendants are distinct from the Opioid Marketing Enterprise.

715. Upon information and belief, the pattern of racketeering activity alleged herein is continuing as of the date of this complaint, and continue into the future unless enjoined by this Court.

716. The racketeering activities conducted by the RICO Marketing Defendants, Janssen, Front Groups and KOLs amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive Pennsylvania consumers, prescribers, regulators and Plaintiff. Each separate use of the U.S. Mail and/or interstate wire facilities employed by

Defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Pennsylvania consumers, prescribers, regulators and Plaintiff. The RICO Marketing Defendants and Janssen have engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the Opioid Marketing Enterprise.

717. Each of the RICO Marketing Defendants and Janssen aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

718. As described herein, the RICO Marketing Defendants and Janssen engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant money and revenue from the marketing and sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

719. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

720. The RICO Marketing Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property. The RICO Marketing Defendants' pattern of racketeering activity logically, substantially and foreseeably caused an opioid epidemic. Plaintiff's injuries, as described below, were not

unexpected, unforeseen or independent.[276] Rather, as Plaintiff alleges, the RICO Marketing Defendants and Janssen knew that the opioids were unsuited to treatment of long-term chronic, non- acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse.[277] Nevertheless, the RICO Marketing Defendants and Janssen engaged in a scheme of deception that utilized the mail and wires in order to carry-out the Opioid Marketing Enterprises' fraudulent scheme, thereby increasing sales of their opioid products

721. It was foreseeable and expected that the RICO Marketing Defendants and Janssen creating and then participating in the Opioid Marketing Enterprise through a pattern of racketeering activities to carry-out their fraudulent scheme would lead to a nationwide opioid epidemic, including increased opioid addiction and overdose.[278]

722. Specifically, the RICO Marketing Defendants' creating and then participating in the Opioid Marketing Enterprise through a pattern of racketeering activities to carry-out their fraudulent scheme has injured Plaintiff in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic. Plaintiff's injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include:

a. Losses caused by the decrease in funding available for Plaintiff's public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;
b. Costs for providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;
c. Costs of training emergency and/or first responders in the proper treatment of drug overdoses, including the administration of naloxone—an opioid antagonist

[276] *Travelers Prop. Cas. Co. of Am. v. Actavis, Inc*., 16 Cal. App. 5th 1026, 1030 (2017).
[277] Id. at 1041.
[278] *Id*.

used to block the deadly effects of opioids in the context of overdose;

d. Costs associated with emergency responses by police officers, firefighters, and emergency and/or first responders to opioid overdoses, including the administration of naloxone;

e. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;

f. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population;

g. Loss of tax revenue due to the decreased efficiency and size of the working population in Plaintiff's communities; and

h. Costs associated with clean-up of public parks, spaces, and facilities of needles and other debris and detritus of opioid addiction.

723. Plaintiff's injuries were directly and thus proximately caused by these Defendants' racketeering activities because they were the logical, substantial and foreseeable cause of Plaintiff's injuries. But for the opioid-addiction epidemic the RICO Marketing Defendants created through their Opioid Marketing Enterprise, Plaintiff would not have lost money or property.

724. Plaintiff is the most directly harmed entity and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

725. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*, actual damages; treble damages; equitable and/or injunctive relief in the form of court-supervised corrective communication, actions and programs; forfeiture as deemed proper by the Court; attorney's fees; all costs and expenses of suit; and pre- and post-judgment interest.

COUNT II
RICO, 18 U.S.C. § 1964(c) – Opioid Supply Chain Enterprise
(Against Defendants Purdue, Cephalon, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, and AmerisourceBergen (the "RICO Supply Chain Defendants"))

726. Plaintiff repeats, re-alleges, and incorporates by reference each and every allegation set forth above as if fully set forth herein.

727. At all relevant times, the RICO Supply Chain Defendants were and are "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

728. The RICO Supply Chain Defendants together formed an association-in-fact enterprise, the Opioid Supply Chain Enterprise, for the purpose of increasing the quota for and profiting from the increased volume of opioid sales in the United States. The Opioid Supply Chain Enterprise is an association-in-fact enterprise within the meaning of § 1961. The Opioid Supply Chain Enterprise consists of the RICO Supply Chain Defendants.

729. The RICO Supply Chain Defendants were members of the Healthcare Distribution Alliance (the "HDA"). Each of the RICO Supply Chain Defendants is a member, participant, and/or sponsor of the HDA, and has been since at least 2006, and utilized the HDA to form the interpersonal relationships of the Opioid Supply Chain Enterprise and to assist them in engaging in the pattern of racketeering activity that gives rise to this Count.

730. At all relevant times, the Opioid Supply Chain Enterprise: (a) had an existence separate and distinct from each of the RICO Supply Chain Defendants; (b) was separate and distinct from the pattern of racketeering in which the RICO Supply Chain Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the RICO Supply Chain Defendants; (d) was characterized by interpersonal relationships among the RICO Supply Chain Defendants; (e) had sufficient longevity for the enterprise to

pursue its purpose; and (f) functioned as a continuing unit. Each member of the Opioid Supply Chain Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid quotas and resulting sales.

731. The RICO Supply Chain Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public by knowingly conducting or participating in the conduct of the Opioid Supply Chain Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud), and in doing so violated 18 U.S.C. §§ 1962(c) and (d).

732. The RICO Supply Chain Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.* violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Supply Chain Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Supply Chain Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Supply Chain Enterprise. The RICO Supply Chain Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

733. The RICO Supply Chain Defendants also conducted and participated in the conduct of the affairs of the Opioid Supply Chain Enterprise through a pattern of racketeering activity by the felonious manufacture, importation, receiving, concealment, buying, selling, or

otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

734. The RICO Supply Chain Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 843(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of § 843(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 843(d)(1).

735. Each of the RICO Supply Chain Defendants is a registrant as defined in the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

736. The RICO Supply Chain Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a. Mail Fraud: The RICO Supply Chain Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

b. Wire Fraud: The RICO Supply Chain Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

737. Controlled Substance Violations: The RICO Supply Chain Defendants who are Distributor Defendants violated 21 U.S.C. § 823 by knowingly or intentionally furnishing false or fraudulent information in, and/or omitting material information from, documents filed with the

DEA.

738. The RICO Supply Chain Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

739. The RICO Supply Chain Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

740. The RICO Supply Chain Defendants hid from the general public and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities about the reality of the suspicious orders that the RICO Supply Chain Defendants were filling on a daily basis – leading to the diversion of hundreds of millions of doses of prescriptions opioids into the illicit market.

741. The RICO Supply Chain Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

742. Indeed, for the Defendants' fraudulent scheme to work, each of the RICO Supply Chain Defendants had to agree to implement similar tactics regarding manufacturing prescription opioids and refusing to report suspicious orders.

743. As described herein, the RICO Supply Chain Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

744. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiff's business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Supply Chain Defendants. The predicate acts were committed or caused to be committed by the RICO Supply Chain Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

745. The pattern of racketeering activity alleged herein and the Opioid Supply Chain Enterprise are separate and distinct from each other. Likewise, the RICO Supply Chain Defendants are distinct from the enterprise.

746. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

747. Many of the precise dates of the RICO Supply Chain Defendants' criminal actions at issue here have been hidden by Defendants and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Supply Chain Enterprise alleged herein depended upon secrecy

748. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

749. It was foreseeable to the RICO Supply Chain Defendants that Plaintiff would be harmed when they refused to report and halt suspicious orders, because their violation of the duties imposed by the CSA and Code of Federal Regulations allowed the widespread diversion of prescription opioids out of appropriate medical channels and into the illicit drug market—causing the opioid epidemic that the CSA intended to prevent.

750. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

751. The RICO Supply Chain Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property. The RICO Supply Chain Defendants' pattern of racketeering activity, including their refusal to identify, report and halt suspicious orders of controlled substances, logically, substantially and foreseeably caused an opioid epidemic. Plaintiff was injured by the RICO Supply Chain Defendants' pattern of racketeering activity and the opioid epidemic that they created.

752. The RICO Supply Chain Defendants knew that the opioids they manufactured and supplied were unsuited to treatment of long-term, chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse.[279] Nevertheless, the RICO Supply Chain Defendants engaged in a scheme of deception, that utilized the mail and wires as part of their fraud, in order to increase sales of their opioid products by refusing to identify, report suspicious orders of prescription opioids that they knew were highly addictive, subject to abuse, and were actually being diverted into the illegal market.[280]

753. The RICO Supply Chain Defendants' predicate acts and pattern of racketeering activity were a cause of the opioid epidemic which has injured Plaintiff in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic.

754. Specifically, Plaintiff's injuries, as alleged throughout this complaint, and

[279] *Travelers Prop. Cas. Co. of Am. v. Actavis, Inc*., 16 Cal. App. 5th 1026, 1030 (2017).
[280] *Id.* at 1041.

expressly incorporated herein by reference, include:

a. Losses caused by the decrease in funding available for Plaintiff's public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;

b. Costs for providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;

c. Costs of training emergency and/or first responders in the proper treatment of drug overdoses;

d. Costs associated with providing police officers, firefighters, and emergency and/or first responders with naloxone—an opioid antagonist used to block the deadly effects of opioids in the context of overdose;[281]

e. Costs associated with emergency responses by police officers, firefighters, and emergency and/or first responders to opioid overdoses;

f. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;

g. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population;

h. Costs associated with increased burden on Plaintiff's judicial systems, including increased security, increased staff, and the increased cost of adjudicating criminal matters due to the increase in crime directly resulting from opioid addiction; and

i. Loss of tax revenue due to the decreased efficiency and size of the working population in Plaintiff's communities.

755. Plaintiff's injuries were proximately caused by Defendants' racketeering activities because they were the logical, substantial and foreseeable cause of Plaintiff's injuries. But for the opioid-addiction epidemic created by Defendants' conduct, Plaintiff would not have lost money or property.

[281] In 2017, Lehigh County was in the top five of Pennsylvania's 67 counties with the most reported naloxone administrations by law enforcement. *See* https://www.dea.gov/sites/default/files/2018-10/Opioid%20threat%20in%20Pennsylvania%20FINAL.pdf

756. Plaintiff's injuries were directly caused by the RICO Supply Chain Defendants' pattern of racketeering activities.

757. Plaintiff is most directly harmed and there are no other plaintiffs better suited to seek a remedy for the economic harms at issue here.

758. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*, actual damages; treble damages; equitable and/or injunctive relief in the form of court-supervised corrective communication, actions and programs; forfeiture as deemed proper by the Court; attorney's fees; all costs and expenses of suit; and pre- and post-judgment interest, including, *inter alia*:

a. Actual damages and treble damages, including pre-suit and post-judgment interest;

b. An order enjoining any further violations of RICO;

c. An order enjoining any further violations of any statutes alleged to have been violated in this Complaint;

d. An order enjoining the commission of any tortious conduct, as alleged in this Complaint;

e. An order enjoining any future marketing or misrepresentations regarding the health benefits or risks of prescription opioids use, except as specifically approved by the FDA;

f. An order enjoining any future marketing of opioids through non-branded marketing including through the Front Groups, KOLs, websites, or in any other manner alleged in this Complaint that deviates from the manner or method in which such marketing has been approved by the FDA;

g. An order enjoining any future marketing to vulnerable populations, including but not limited to, persons over the age of fifty-five, anyone under the age of twenty-one, and veterans;

h. An order compelling the Defendants to make corrective advertising statements that shall be made in the form, manner and duration as determined by the Court, but not less than print advertisements in national and regional newspapers and medical journals, televised broadcast on major television networks, and displayed on their websites, concerning: (1) the risk of addiction among patients taking opioids for pain; (2) the ability to manage the risk of addiction; (3) pseudoaddiction

is really addiction, not a sign of undertreated addiction; (4) withdrawal from opioids is not easily managed; (5) increasing opioid dosing presents significant risks, including addiction and overdose; (6) long term use of opioids has no demonstrated improvement of function; (8) use of time-released opioids does not prevent addiction; (9) abuse-deterrent formulations do not prevent opioid abuse; and (10) that manufacturers and distributors have duties under the CSA to monitor, identify, investigate, report and halt suspicious orders and diversion but failed to do so;

i. An order enjoining any future lobbying or legislative efforts regarding the manufacturer, marketing, distribution, diversion, prescription, or use of opioids;

j. An order requiring all Defendants to publicly disclose all documents, communications, records, data, information, research or studies concerning the health risks or benefits of opioid use;

k. An order prohibiting all Defendants from entering into any new payment or sponsorship agreement with, or related to, any: Front Group, trade association, doctor, speaker, CME, or any other person, entity, or association, regarding the manufacturer, marketing, distribution, diversion, prescription, or use of opioids;

l. An order establishing a National Foundation for education, research, publication, scholarship, and dissemination of information regarding the health risks of opioid use and abuse to be financed by the Defendants in an amount to be determined by the Court;

m. An order enjoining any diversion of opioids or any failure to monitor, identify, investigate, report and halt suspicious orders or diversion of opioids;

n. An order requiring all Defendants to publicly disclose all documents, communications, records, information, or data, regarding any prescriber, facility, pharmacy, clinic, hospital, manufacturer, distributor, person, entity or association regarding suspicious orders for or the diversion of opioids;

o. An order divesting each Defendant of any interest in, and the proceeds of any interest in, the Marketing and Supply Chain Enterprises, including any interest in property associated with the Marketing and Supply Chain Enterprises;

p. Dissolution and/or reorganization of any trade industry organization, Front Group, or any other entity or association associated with the Marketing and Supply Chain Enterprises identified in this Complaint, as the Court sees fit;

q. Dissolution and/or reorganization of any Defendant named in this Complaint as the Court sees fit;

r. Suspension and/or revocation of the license, registration, permit, or prior approval granted to any Defendant, entity, association or enterprise named in the Complaint regarding the manufacture or distribution of opioids;

s. Forfeiture as deemed appropriate by the Court; and

t. Attorney's fees and all costs and expenses of suit.

COUNT III
PUBLIC NUISANCE
(Against all Defendants)

759. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

760. Each Defendant is liable for public nuisance because its conduct at issue has caused an unreasonable and substantial interference with a right common to the general public, which is the proximate cause of, and/or substantial factor leading to, Plaintiff's injury. *See* Restatement Second, Torts § 821B.

761. By causing dangerously addictive drugs to flood its community, and to be diverted for illicit purposes, in contravention of federal and State law, each Defendant has injuriously affected rights common to the general public, specifically including the rights of the people of Allentown to public health, public safety, public peace, public comfort, and public convenience. The public nuisance caused by Defendants' diversion of dangerous drugs has caused substantial annoyance, inconvenience, and injury to the public.

762. By falsely marketing and selling dangerously addictive opioid drugs diverted from a legitimate medical, scientific, or industrial purpose, Defendants have committed a course of conduct that injuriously affects the safety, health, and morals of the people of Allentown.

763. By failing to maintain a closed system that guards against diversion of dangerously addictive drugs for illicit purposes, Defendants injuriously affected public rights,

including the right to public health, public safety, public peace, and public comfort of the people of the Plaintiff's Community.

764. All Defendants have intentionally and/or unlawfully created a nuisance.

765. The residents of Plaintiff's Community have a common right to be free from conduct that creates an unreasonable jeopardy to the public health, welfare and safety, and to be free from conduct that creates a disturbance and reasonable apprehension of danger to person and property.

766. Defendants intentionally, unlawfully, and recklessly manufacture, market, distribute, and sell prescription opioids that Defendants know, or reasonably should know, will be diverted, causing widespread distribution of prescription opioids in and/or to Plaintiff's Community, resulting in addiction and abuse, an elevated level of crime, death and injuries to the residents of Plaintiff's Community, a higher level of fear, discomfort and inconvenience to the residents of Plaintiff's Community, and direct costs to Plaintiff's Community.

767. Defendants have unlawfully and/or intentionally caused and permitted dangerous drugs under their control to be diverted such as to injure the Plaintiff's Community and its residents.

768. Defendants have unlawfully and/or intentionally distributed opioids or caused opioids to be distributed without maintaining effective controls against diversion. Such conduct was illegal. Defendants' failures to maintain effective controls against diversion include Defendants' failure to effectively monitor for suspicious orders, report suspicious orders, and/or stop shipment of suspicious orders.

769. Defendants have caused a significant and unreasonable interference with the public health, safety, welfare, peace, comfort and convenience, and ability to be free from

disturbance and reasonable apprehension of danger to person or property.

770. Defendants' conduct in illegally distributing and selling falsely marketed prescription opioids, or causing such opioids to be distributed and sold, where Defendants know, or reasonably should know, such opioids will be diverted and possessed and/or used illegally in Plaintiff's Community is of a continuing nature.

771. Defendants' actions have been of a continuing nature and have produced a significant effect upon the public's rights, including the public's right to health and safety.

772. The ongoing violation of a rule or law controlling the distribution of a drug of abuse in Plaintiff's Community and the State is a public nuisance.

773. Defendants' distribution of opioids while failing to maintain effective controls against diversion was proscribed by statute and regulation.

774. Defendants' ongoing conduct produces an ongoing nuisance, as the prescription opioids that they allow and/or cause to be illegally distributed and possessed in Plaintiff's Community will be diverted, leading to abuse, addiction, crime, and public health costs.

775. Because of the continued use and addiction caused by these illegally distributed opioids, the public will continue to fear for its health, safety and welfare, and will be subjected to conduct that creates a disturbance and reasonable apprehension of danger to person and property.

776. Defendants know, or reasonably should know, that their conduct will have an ongoing detrimental effect upon the public health, safety and welfare, and the public's ability to be free from disturbance and reasonable apprehension of danger to person and property.

777. Defendants know, or reasonably should know, that their conduct causes an unreasonable invasion of the public right to health, safety and welfare and the public's ability to be free from disturbance and reasonable apprehension of danger to person and property.

778. Defendants are aware, and at a bare minimum certainly should be aware, of the unreasonable interference that their conduct has caused in Plaintiff's Community. Defendants are in the business of manufacturing, marketing, selling, and distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous under federal law. *See, e.g.*, 21 U.S.C. § 812 (b)(2).

779. Defendants' conduct in marketing, distributing, and selling prescription opioids which all Defendants know, or reasonably should know, likely will be diverted for non-legitimate, non-medical use, creates a strong likelihood that these illegal distributions of opioids will cause death and injuries to residents in Plaintiff's Community and otherwise significantly and unreasonably interfere with public health, safety and welfare, and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

780. It is, or should be, reasonably foreseeable to Defendants that their conduct will cause deaths and injuries to residents in Plaintiff's Community, and will otherwise significantly and unreasonably interfere with public health, safety and welfare, and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

781. The prevalence and availability of diverted prescription opioids in the hands of irresponsible persons and persons with criminal purposes in Plaintiff's Community not only causes deaths and injuries, but also creates a palpable climate of fear among residents in Plaintiff's Community where opioid diversion, abuse, addiction are prevalent and where diverted opioids tend to be used frequently.

782. Defendants' conduct makes it easier for persons to divert prescription opioids, constituting a dangerous threat to the public.

783. Defendants' actions were, at the least, a substantial factor in opioids becoming

widely available and widely used for non-medical purposes. Because of Defendants' special positions within the closed system of opioid distribution, without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

784. The presence of diverted prescription opioids in Plaintiff's Community, and the consequence of prescription opioids having been diverted in Plaintiff's Community, proximately result in and/or substantially contribute to the creation of significant costs to the Plaintiff and to Plaintiff's Community in order to enforce the law, equip its police force and treat the victims of opioid abuse and addiction.

785. Stemming the flow of illegally distributed prescription opioids, and abating the nuisance caused by the illegal flow of opioids, will help to alleviate this problem, save lives, prevent injuries and make Plaintiff's Community a safer place to live.

786. Defendants' conduct is a direct and proximate cause of and/or a substantial contributing factor to opioid addiction and abuse in Plaintiff's Community, costs borne by Plaintiff's Community and the Plaintiff, and a significant and unreasonable interference with public health, safety and welfare, and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

787. Defendants' conduct constitutes a public nuisance and, if unabated, will continue to threaten the health, safety and welfare of the residents of Plaintiff's Community, creating an atmosphere of fear and addiction that tears at the residents' sense of well-being and security. Plaintiff has a clearly ascertainable right to abate conduct that perpetuates this nuisance

788. Defendants created an intentional nuisance. Defendants' actions created and expanded the abuse of opioids, which are dangerously addictive, and the ensuing associated

plague of prescription opioid and heroin addiction. Defendants knew the dangers to public health and safety that diversion of opioids would create in Plaintiff's Community, however, Defendants intentionally and/or unlawfully failed to maintain effective controls against diversion through proper monitoring, reporting and refusal to fill suspicious orders of opioids. Defendants intentionally and/or unlawfully distributed opioids or caused opioids to be distributed without reporting or refusing to fill suspicious orders or taking other measures to maintain effective controls against diversion. Defendants intentionally and/or unlawfully continued to ship and failed to halt suspicious orders of opioids, or caused such orders to be shipped. Defendants intentionally and/or unlawfully marketed opioids in manners they knew to be false and misleading. Such actions were inherently dangerous.

789. Defendants knew the prescription opioids have a high likelihood of being diverted. It was foreseeable to Defendants that where Defendants distributed prescription opioids or caused such opioids to be distributed without maintaining effective controls against diversion, including monitoring, reporting, and refusing shipment of suspicious orders, that the opioids would be diverted, and create an opioid abuse nuisance in Plaintiff's Community.

790. Defendants' actions also created a nuisance by acting recklessly, negligently and/or carelessly, in breach of their duties to maintain effective controls against diversion, thereby creating an unreasonable risk of harm.

791. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

792. The damages available to the Plaintiff include, *inter alia*, recoupment of governmental costs, flowing from an ongoing and persistent public nuisance which the Plaintiff

seeks to abate. Defendants' conduct is ongoing and persistent, and the Plaintiff seeks all damages flowing from Defendants' conduct. Plaintiff further seeks to abate the nuisance and harm created by Defendants' conduct.

793. As a direct result of Defendants' conduct, the Plaintiff and Plaintiff's Community have suffered actual injury and damages including, but not limited to, significant expenses for child, police, emergency, public health, court, corrections and other services. The Plaintiff here seeks recovery for its own harm.

794. The Plaintiff and Plaintiff's Community have sustained specific and special injuries because their damages include, inter alia, health services, law enforcement expenditures, and costs related to opioid addiction treatment and overdose prevention.

795. The Plaintiff further seeks to abate the nuisance created by all Defendants' unreasonable, unlawful, intentional, ongoing, continuing, and persistent actions and omissions and interference with a right common to the public.

796. Defendants' intentional and unlawful actions and omissions and unreasonable interference with a right common to the public are of a continuing nature.

797. Defendants are aware, and at a bare minimum certainly should be aware, of the unreasonable interference that their conduct has caused in Plaintiff's Community. Defendants are in the business of manufacturing or distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because *inter alia* these drugs are defined under federal and state law as substances posing a high potential for abuse and severe addiction. Defendants created an intentional nuisance. Defendants' actions created and expanded the abuse of opioids, drugs specifically codified as constituting severely harmful substances.

798. The public nuisance created by Defendants' actions is substantial and

unreasonable -- it has caused and continues to cause significant harm to Plaintiff's Community, and the harm inflicted outweighs any offsetting benefit. The staggering rates of prescription opioid and heroin use resulting from all Defendants' abdication of their gate-keeping and diversion prevention duties, and the fraudulent marketing activities by Defendants Purdue, Cephalon, Endo, Actavis, and Mallinckrodt, have caused harm to the entire community that includes, but is not limited to the following:

a. The high rates of use leading to unnecessary opioid abuse, addiction, overdose, injuries, and deaths.

b. Even those residents of Plaintiff's Community who have never taken opioids have suffered from the public nuisance arising from Defendants' abdication of their gate- keeper duties and fraudulent promotions. Many residents have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.

c. Even children have fallen victim to the opioid epidemic. Easy access to prescription opioids made opioids a recreational drug of choice among teenagers. Infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts.

d. The opioid epidemic has increased health care costs.

e. Employers have lost the value of productive and healthy employees.

f. Defendants' conduct created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury.

g. Defendants' dereliction of duties and/or fraudulent misinformation campaign pushing dangerous drugs resulted in a diverted supply of narcotics to sell, and the ensuing demand of addicts to buy them. More prescription opioids sold by Defendants led to more addiction, with many addicts turning from prescription opioids to heroin. People addicted to opioids frequently require increasing levels of opioids, and many turned to heroin as a foreseeable result.

h. The diversion of opioids into the secondary, criminal market and the increased number of individuals who abuse or are addicted to opioids increased the demands on health care services and law enforcement.

i. The significant and unreasonable interference with the public rights caused by Defendants' conduct taxed the human, medical, public health, law enforcement, and financial resources of the Plaintiff's Community.

j. Defendants' interference with the comfortable enjoyment of life in the Plaintiff's Community is unreasonable because there is little social utility to opioid diversion and abuse, and any potential value is outweighed by the gravity of the harm inflicted by Defendants' actions.

799. Plaintiff and Plaintiff's Community have sustained specific and special injuries because its damages include *inter alia* health services, court, and law enforcement expenditures, as described in this Complaint.

800. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' fraudulent activity and fraudulent misrepresentations. Plaintiff does not seek damages for physical personal injury or any physical damage to property caused by Defendants' actions.

801. Plaintiff seeks all legal and equitable relief as allowed by law, other than such damages disavowed herein, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT IV
NEGLIGENCE AND NEGLIGENT MISREPRESENTATION
(Against all Defendants)

802. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows

803. Plaintiff seeks economic damages which were the foreseeable result of Defendants' intentional and/or unlawful actions and omissions.

804. Under State law, to establish actionable negligence, one must show in addition to the existence of a duty, a breach of that duty, and injury resulting proximately therefrom and/or was substantially caused thereby. All such essential elements exist here.

805. Further, as Section 302B of the Restatement of Torts provides: "An act or an

omission may be negligent if the actor realizes or should realize that it involves an unreasonable risk of harm to another through the conduct of the other or a third person which is intended to cause harm, even though such conduct is criminal."

806. Each Defendant had an obligation to exercise reasonable care in manufacturing, marketing, selling, and distributing highly dangerous opioid drugs to the State and Plaintiff's Community.

807. Each Defendant had an obligation to exercise due care in manufacturing, marketing, selling, and distributing highly dangerous opioid drugs in the State and Plaintiff's Community.

808. Each Defendant owed a duty to the Plaintiff, and to the public in the Plaintiff's Community, because the injury was foreseeable, and in fact foreseen, by all Defendants.

809. Reasonably prudent manufacturers and distributors of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities, and the significant costs which would be imposed upon the governmental entities associated with those communities. The closed system of opioid distribution whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, and wherein all links in the chain have a duty to prevent diversion, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse.

810. Reasonably prudent manufacturers of pharmaceutical products would know that aggressively pushing highly addictive opioids for chronic pain would result in the severe harm of addiction, foreseeably causing patients to seek increasing levels of opioids, frequently turning to the illegal drug market as a result of a drug addiction that was foreseeable to Defendants Purdue, Cephalon, Endo, Actavis, and Mallinckrodt.

811. Moreover, Defendants were repeatedly warned by law enforcement of the unlawfulness and consequences of their actions and omissions.

812. The escalating amounts of addictive drugs flowing through Defendants' businesses, and the sheer volume of these prescription opioids, further alerted Defendants that addiction was fueling increased consumption and that legitimate medical purposes were not being served.

813. As described above in allegations expressly incorporated herein, all Defendants breached their duties to exercise due care in the business of wholesale distribution of dangerous opioids, which are Schedule II Controlled Substances, by failing to monitor for, failing to report, and filling highly suspicious orders time and again. Because the very purpose of these duties was to prevent the resulting harm – diversion of highly addictive drugs for non-medical purposes – the causal connection between Defendants' breaches of duties and the ensuing harm was entirely foreseeable.

814. As described elsewhere in the Complaint in allegations expressly incorporated herein, all Defendants misrepresented their compliance with their duties under the law, concealed their noncompliance, and shipped suspicious orders of opioids to Plaintiff's Community and destinations from which they knew opioids were likely to be diverted into Plaintiff's Community, in addition to other misrepresentations alleged and incorporated herein.

815. As described elsewhere in the Complaint in allegations expressly incorporated herein, Defendants Purdue, Cephalon, Endo, Actavis, and Mallinckrodt breached their duties to exercise due care in the course of carrying out their business of being pharmaceutical manufacturers of dangerous opioids, which are Schedule II Controlled Substances, and by misrepresenting the nature of the drugs and aggressively promoting them for chronic pain for

which they knew the drugs were not safe or suitable, upon which the Plaintiff's Community, its residents, and Plaintiff reasonably relied.

816. The Marketing Conspirators misrepresented and concealed the addictive nature of prescription opioids and their lack of suitability for chronic pain, in addition to other misrepresentations alleged and incorporated herein.

817. All Defendants breached their duties to prevent diversion and report and halt suspicious orders, and all Defendants misrepresented their compliance with their legal duties.

818. Defendants' breaches were intentional and/or unlawful, and Defendants' conduct was willful, wanton, malicious, reckless, oppressive, and/or fraudulent.

819. The causal connection between Defendants' breaches of duties and misrepresentations and the ensuing harm was entirely foreseeable.

820. As described above in allegations expressly incorporated herein, Defendants' breaches of duty and misrepresentations caused, bears a causal connection with, and/or proximately resulted in the damages sought herein.

821. Defendants were selling dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Defendants knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than medical, scientific, or industrial channels. However, Defendants breached their duties to monitor for, report, and halt suspicious orders, breached their duties to prevent diversion, and, further, misrepresented what their duties were and their compliance with their legal duties.

822. The Defendants failed to disclose the material facts that, *inter alia*, they were not in compliance with laws and regulations requiring that they maintain a system to prevent diversion, protect against addiction and severe harm, and specifically monitor, investigate,

report, and refuse suspicious orders. But for these material factual omissions, Defendants would not have been able to sell opioids.

823. As alleged herein, each Marketing Conspirator wrongfully represented that the opioid prescription medications they manufactured, marketed, and sold had characteristics, uses, or benefits that they do not have. The Marketing Conspirators also wrongfully misrepresented that the opioids were safe and effective when such representations were untrue, false, and misleading.

824. Because of the dangerously addictive nature of these drugs, which the Marketing Conspirators concealed and misrepresented, they lacked medical value, and in fact caused addiction and overdose deaths.

825. The Marketing Conspirators made deceptive representations about the use of opioids to treat chronic non-cancer pain. Each Marketing Conspirator also omitted or concealed material facts and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids. Each Defendant's omissions rendered even their seemingly truthful statements about opioids deceptive, and the Plaintiff's Community, its residents, and Plaintiff reasonably relied upon said misrepresentations.

826. Defendants' unlawful and/or intentional actions create a rebuttable presumption of negligence under State law.

827. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' actions and omissions. Plaintiff does not seek damages for physical personal injury or any physical damage to property caused by Defendants' actions.

828. Plaintiff seeks all legal and equitable relief as allowed by law, other than such damages disavowed herein, including *inter alia* injunctive relief, restitution, disgorgement of

profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT V
NEGLIGENCE PER SE - Failure to Guard Against Diversion
(Against Distributor Defendants)

829. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

830. Violations of statutes and regulations support a cause of action for negligence per se where the harm sustained by Defendants' statutory or regulatory violations is the type sought to be prevented and the violations proximately caused the Plaintiff's injuries.

831. "The federal laws and requirements which Pennsylvania incorporates into its own laws require Defendants to act as gatekeepers guarding against the diversion of the highly addictive, dangerous opioid drugs.

832. For example, the PCSA tracks and incorporates federal regulations that require all distributors of controlled substances to "design and operate a system to disclose… suspicious orders of controlled substances… include[ing] orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. 35 Pa.C.S.A. § 780-112(c) (incorporating 21 C.F.R. § 1301.74(b)).

833. Distributor Defendants, moreover, are subject to both the Pennsylvania Wholesale Prescription Drug Distributors License Act ("Pennsylvania WPDDLA"), 63 P.S. §391.6, et seq. and the Federal Controlled Substances Act, 21 U.S.C. §801, et seq.

834. Collectively and individually, the PCSA, the Pennsylvania WPDDLA and the Federal Controlled Substances Act create statutory standards that require prescription drug distributors to maintain and monitor a closed chain of distribution, and to detect, report, inspect,

and halt suspicious orders so as to prevent the black market diversion of controlled substances.

835. More specifically, the Pennsylvania WPDDLA requires that the Distributor Defendants know the average number of their opioid prescriptions filled daily, how the percentage of controlled substances compares to a customer's overall purchases, how the pharmacist fulfills its responsibility to ensure that prescriptions are being fulfilled for legitimate medical purposes, and the identities of "pill mill" outlets that are the pharmacists' most frequent prescribers.

836. The Distributor Defendants have each paid substantial fines for their violation of the Federal Controlled Substances Act, which tracks their obligations under the Pennsylvania WPDDLA.

837. The Distributor Defendants' violations of the statutory standards set forth in the Pennsylvania WPDDLA and the Federal Controlled Substances Act constitute negligence per se under Pennsylvania law.

838. Distributor Defendants' violations of the state and federal statutes, and public safety regulations cited herein were and are a substantial factor in the injuries and damages sustained by Plaintiff.

839. It was foreseeable that Distributor Defendants' breach of statutory and regulatory laws described herein would result in the damages sustained.

840. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' negligence per se.

841. Plaintiff seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including, inter alia, injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the

Distributor Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT VI
CIVIL CONSPIRACY
(Against All Defendants)

842. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

843. As set forth herein, Defendants engaged in a civil conspiracy to create a public nuisance in conjunction with their unlawful marketing, sale, distribution and/or diversion of opioids into the State and Plaintiff's Community.

844. As set forth herein, Defendants engaged in a civil conspiracy to commit fraud and misrepresentation in conjunction with their unlawful distribution and diversion of opioids into the State and Plaintiff's Community.

845. Distributor Defendants and Defendants Purdue, Cephalon, Endo, Actavis and Mallinckrodt unlawfully failed to act to prevent diversion and failed to monitor for, report, and prevent suspicious orders of opioids.

846. Defendants Purdue, Cephalon, Endo, Actavis, and Mallinckrodt further unlawfully marketed opioids in the State and Plaintiff's Community in furtherance of that conspiracy.

847. Defendants acted tortiously in agreement and/or in concert with each other and/or in pursuit of a common design, and/or Defendants knew each other's conduct constituted a breach of their legal duties and provided substantial assistance and/or encouragement in the conduct.

848. Defendants' conspiracy is a continuing conspiracy, and the overt acts performed in compliance with the conspiracy's objective(s) are ongoing and/or have occurred within the

last year.

849. Defendants acted with agreement and a common understanding or design to commit unlawful acts and/or lawful acts unlawfully, as alleged herein, and acted purposely, without a reasonable or lawful excuse, to create the injuries alleged herein.

850. Defendants acted with malice, purposely, intentionally, unlawfully, and without a reasonably or lawful excuse.

851. Defendants' conspiracy, and Defendants' actions and omissions in furtherance thereof, proximately caused and/or substantially contributed to the direct and foreseeable losses alleged herein.

852. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' civil conspiracy. Plaintiff does not seek damages for physical, personal injury or any physical damage to property caused by Defendants' actions.

853. Plaintiff seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

COUNT VII
UNJUST ENRICHMENT
(Against All Defendants)

854. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

855. Defendants acted willfully, wantonly, and with conscious disregard of the rights of the Plaintiff and its residents

856. As an expected and intended result of their conscious wrongdoing as set forth in

this Complaint (including not only each Defendant's respective wrongdoing but also the wrongful conduct of other Defendants), Defendants have profited and benefited from billions of dollars' worth of opioid purchases by Plaintiff and others.

857. In exchange for the opioid purchases, and at the time Plaintiff and others made these payments, Plaintiff and others expected that Defendants had provided all of the necessary and accurate information regarding the risks of the opioids and had not misrepresented any material facts regarding those risks.

858. Defendants, through the wrongful conduct described above (including not only each Defendant's respective wrongdoing but also the wrongful conduct of other Defendants) have been unjustly enriched at the expense of Plaintiff.

859. In equity and good conscience, it would be unjust and inequitable to permit Defendants to enrich themselves at the expense of the Plaintiff and its residents.

860. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' conduct. Plaintiff does not seek damages regarding individual residents' issues regarding physical personal injury or any physical damage to property caused by Defendants' actions.

861. Plaintiff seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

COUNT VIII
FRAUD AND FRAUDULENT MISREPRESENTATION
(Against All Defendants)

862. Plaintiff incorporates by reference all other paragraphs of this Complaint as if

fully set forth herein, and further alleges as follows.

863. Defendants had a general duty not to actively deceive. Defendants violated this duty by making knowingly false statements and omitting and/or concealing information which made statements by Defendants knowingly false. Defendants acted intentionally and/or unlawfully.

864. As alleged herein, Defendants Purdue, Cephalon, Endo, Actavis, and Mallinckrodt made false statements regarding their compliance with state and federal law regarding their duties to prevent diversion, their duties to monitor, report and halt suspicious orders, and/or concealed their noncompliance with these requirements.

865. As alleged herein, the Marketing Conspirators engaged in false representations and concealments of material fact regarding the use of opioids to treat chronic non-cancer pain.

866. As alleged herein, Defendants knowingly and/or intentionally made representations that were false. Defendants had a duty to disclose material facts and concealed them. These false representations and concealed facts were material to the conduct and actions at issue. Defendants made these false representations and concealed facts with knowledge of the falsity of their representations, and did so with the intent of misleading Plaintiff, Plaintiff's community, the public, and persons on whom Plaintiff relied.

867. These false representations and concealments were reasonably calculated to deceive Plaintiff, Plaintiff's Community, and the physicians who prescribed opioids for persons in Plaintiff's Community, were made with the intent to deceive, and did in fact deceive these persons, Plaintiff, and Plaintiff's Community.

868. Plaintiff, Plaintiff's Community, and the physicians who prescribed opioids reasonably relied on these false representations and concealments of material fact.

869. Plaintiff justifiably relied on Defendants' representations and/or concealments, both directly and indirectly. Plaintiff's injuries were proximately caused by this reliance.

870. The injuries alleged by Plaintiff herein were sustained as a direct and proximate cause of Defendants' fraudulent conduct.

871. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' fraudulent activity, including fraudulent misrepresentations and fraudulent concealment. Plaintiff does not seek damages for physical personal injury or any physical damage to property caused by Defendants' actions.

872. Plaintiff seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

PUNITIVE DAMAGES

873. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

874. By engaging in the above-described intentional and/or unlawful acts or practices, Defendants acted with actual malice, wantonly, and oppressively. Defendants acted with conscious disregard to the rights of others and/or in a reckless, wanton, willful, or gross manner. Defendants acted with a prolonged indifference to the adverse consequences of their actions and/or omissions. Defendants acted with a conscious disregard for the rights and safety of others in a manner that had a great probability of causing substantial harm. Defendants acted toward the Plaintiff with fraud, oppression, and/or malice.

875. Defendants were selling and/or manufacturing dangerous drugs statutorily

categorized as posing a high potential for abuse and severe dependence. Thus, Defendants knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than legitimate medical, scientific, or industrial channels. Because of the severe level of danger posed by, and indeed visited upon the State and Plaintiff's Community by, these dangerous drugs, Defendants owed a high duty of care to ensure that these drugs were only used for proper medical purposes. Defendants chose profit over prudence, and the safety of the community, and an award of punitive damages is appropriate, as punishment and a deterrence.

876. By engaging in the above-described wrongful conduct, Defendants also engaged in willful misconduct and exhibited an entire want of care that would raise the presumption of a conscious indifference to consequences and are entitled to punitive damages.

RELIEF

WHEREFORE, the Plaintiff respectfully prays that this Court grant the following relief:

877. Enter Judgment in favor of the Plaintiff in a final order against each of the Defendants;

878. Award the Plaintiff actual damages, compensatory damages, punitive damages, equitable relief, and attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

879. Enjoin from disseminating and/or causing the dissemination of misleading information about the safety and efficacy of opioids, engaging in other unfair or deceptive practices in violation of law and ordering temporary, preliminary or permanent injunction;

880. Enter an order further requiring Defendants to:

a. Provide regular, detailed reports to the City regarding the sale and distribution of Defendants' opioids within the City;

b. Provide, participate in, and support the effective dissemination of accurate information to medical providers, pharmacists, consumers, and others about the risks and benefits of opioids and alternatives to opioids, including information about efficacy and information about the dangers and risks of opioid misuse, addiction, and overdose;

c. Provide and support the provision of naloxone for community distribution, and distribution to patients, families, first responders, personnel, and others;

d. Provide, participate in, and support the effective dissemination of accurate information to medical providers, pharmacists, consumers, and others

about addiction treatment options (including medication assisted treatment), and about the availability and proper use of naloxone;

e. Perform and support a public outreach campaign to inform City residents about the dangers of opioids, to be disseminated via television, radio, print, online, and other means;

f. Provide, participate in, and support accurate detailing efforts regarding opioids and alternatives;

g. Provide, participate in, and support programs to identify and treat addiction;

h. Participate in and support appropriate changes to Electronic Medical Record systems, to ensure default settings and alerts for opioids are appropriate;

i. Participate in, and support, harm reduction efforts, including syringe exchanges, testing and treatment for hepatitis C virus (HCV) and other consequences of opioid addiction, housing services, and drug and syringe disposal;

j. Participate in and support programs to monitor pharmaceutical marketing efforts in the City, including the registration of pharmaceutical representatives and review of their materials and activities relating to prescription opioids; and

k. Fund the cost of detoxification and treatment, including the costs of medications used as part of medication assisted treatment, for every resident in the City currently suffering from opioid addiction attributable to prescription

opioids;

l. Provide, participate in, and support monitoring relating to the opioid crisis, including outcome data and the staff and equipment that will be needed within the City to obtain and organize this data;

m. Participate in, and support, a real-time, City-wide dashboard of opioid-related data, including locations of deaths and non-fatal overdoses and available treatment slots;

n. Such other relief as the Court deems appropriate.

Dated: August 27, 2019

Respectfully Submitted,

LANGER, GROGAN & DIVER, P.C.

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